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| 14. ABSTRACT The Pacific Pediatric Advanced Care Initiative establishes an advanced care Center with ECLS support in Hawaii to support the Pacific Rim. The Center will advance the science of Pediatric Advanced Care through new basic science and simulation research, while providing advanced care to patients, and improving the education and training of Department of Defense (DOD) Health Care providers. The Center will be established and evaluated through existing guidelines for clinical care and education and training. The initial research foci for the Center will be the following: 1. basic science research in ECMO, 2. development of manikinbased, simulation technologies as applied to the ECLS curriculum, 3. develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data. | | | | | |
| 15. SUBJECT TERMS Extracorporeal Life Support (ECLS), Extracorporeal Membrane Oxygenation (ECMO), Simulation, Manikin, Training, Education, Pediatric Intensive Care, Continuing Medical Education (CME) Continuing Education Unit (CEU), Septic shock, pig model, blood substitute | | | | | |
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Introduction

The Pacific Pediatric Advanced Care Initiative has established an advanced care center with ECLS support in Hawaii to support the Pacific Rim. The Center's goal is to advance the science of Pediatric Advanced Care through new basic science and simulation research, while providing advanced care to patients, and improving the education and training of Department of Defense (DOD) Health Care providers. The Center is evaluated through existing guidelines for clinical care and education and training. The major research foci for the Center includes: 1. basic science research in ECMO, and 2. development and evaluation of simulation technologies as applied to pre-ECLS and ECLS curricula. This initiative is a joint venture between Tripler Army Medical Center (TAMC), Kapi'olani Medical Center for Women and Children (KMCWC), Kaiser Permanente Hawaii, University of Hawaii (UH), and the University of Pittsburgh Medical Center (UPMC). The objectives are as follows:

1. Establish a new Center for extracorporeal life support (ECLS) in Hawaii. Ongoing clinical review of results will be conducted to ensure that patient care meets national ECLS benchmarks. ECLS is established and proven standard-of-care technology, which provides advanced levels of care to Pediatric patients with life-threatening, potentially reversible cardiorespiratory failure. In preplanning, it was determined by the consortium that this program would be housed at Kapi'olani Medical Center for Women and Children and jointly staffed by physicians from Tripler, Kaiser, and Kapi'olani.
2. Name a national advisory board. This will function as an oversight panel, and will be instrumental in providing the clinical and educational experts that will help to review the administrative, clinical and educational programs to insure the Center is meeting national guidelines and benchmarks.
3. Develop a basic science research program for the Center. The first study will evaluate the utility of ECMO for management of severe septic shock in a porcine model, and whether the utilization of blood substitutes would impact results. Hormonal and physiologic parameters will be measured, combined with qualitative histologic analyses of end organs. The program will advance the science of ECLS, while providing the groundwork for future Center studies.
4. Develop a manikin-based simulator training curriculum to supplement to traditional training. This training curriculum serves multiple levels of health care providers to include physicians, nurses, perfusionists, and respiratory therapists. Following didactic education, skill acquisition rates of defined tasks and infant simulator survival will be compared both with and without manikin training.
5. Develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data. Patient physiologic variables are affected by pharmacologic and ECMO pump settings. Connecting these interactions through a computer simulation model will provide a valuable training resource for ECMO centers with small case numbers. ECMOjo will be refined using a heuristic evaluation model. Following prototype finalization, scenario-based curriculum will be evaluated on its ability for providers to acquire ECMO skills.

Body

Task 1. To establish a new Hawaii-Pacific Rim extracorporeal life support (ECLS) Center, which provides advanced levels of care to Pediatric patients with life-threatening cardiorespiratory failure; to evaluate the Center's effectiveness in attaining clinical results that meet national ECLS benchmarks.

a. Establish ECLS Hanuola Center at Kapi'olani Medical Center for Women and Children using well-established clinical and referral guidelines, and training curricula.

a.1. ECMO Cases

Currently, case load for the civilian sector has averaged five to six cases annually, with the Center expected to grow to 12 cases per year into the future. Since the opening of the Hanuola ECMO Center, there have been 68 ECMO consults (25 consults in 2008, 22 consults in 2009, 21 consults in 2010), with 18 patients being treated with ECMO (five patients in 2008, five patients in 2009, eight patients in 2010). The caseload at the Hanuola Center falls within the range of average cases for ECMO centers across the US. According to the ELSO database, of the 96 centers that reported patients in 1997, the average number of patients per center was nine (Roy, 2000). See Appendix A.9 for ELSO results for the Hanuola Center.

a.2. Policies and Procedures

The Hanuola Center has worked closely to integrate with several departments and programs at KMCWC. These include the blood bank, blood utilization committee, clinical laboratories, operating room, central supply, pharmacy, respiratory care, Neonatal Intensive Care Unit (NICU) nursing, Pediatric Intensive Care Unit (PICU) nursing, Risk Management and the Pediatric Executive Committee. The development of policies and procedures with other supporting clinical departments has been completed during this reporting period; and monthly ECMO meeting have been scheduled to facilitate ongoing discussion of patient debriefs, system review and educational updates.

a.3. ECMO Transport

During the first year of the Hanuola Center, the need for air and ground ECMO transport systems became a priority due to the unique clinical circumstances of the Hawaii medical community. In order to develop an ECMO transport system extensive planning and coordination of experienced personnel is necessary. The nature of transporting pediatric ECMO patients is often associated with severe instability and possible cardiac arrest. Thus, collaboration with AirMed International and Elliott Aviation has been initiated to design and build the ECMO Transport Sled (ETS).

During this reporting period, Elliott Aviation began construction of the ECMO Transport Sled in mid December 2009 to facilitate the FAA approval process. Construction is at Elliott's expense. The sled was completed in early 2010, whereby Federal Aviation Administration (FAA) approval was sought. The FAA has determined that the ETS will not need a Supplemental Type Certificate to clear it for flight; only the medical base in the aircraft will need a modification of its Certificate in order to transport the ETS. The ETS received structural substantiation for the Hawker Beechjet 400A aircraft from the FAA in March 2010. The paperwork (form 8110-3) is

on file with Elliott Aviation and Hanuola. Transport Protocols have been developed based on existing KMCWC Transport Protocols. Equipment and Supply checklists have been completed as well as power and weight charts.

A funding request for the ETS construction and purchase was submitted to Tripler Army Medical Center and the request has been approved. However, we will not know if TAMC can fund the ETS till 30 June 2011. This is after a determination of funding availability has been made at the Army AMEDD Strategic Technology Clinical Policy Council Meeting held in San Antonio, TX. Unless we hear otherwise, we have reserved funding for the construction. If funding is approved prior to the end date of this contract, the reserved funds will be used to purchase additional ECMO equipment and backup supplies in support of the Center.

a.4. Credentialing

As part of a functioning ECLS Center, proper credentialing is necessary for management of the ECMO program. A number of physicians have been granted privileges to provide routine and emergency clinical care for infant patients on ECLS. This includes 12 Neonatal physicians and 6 Pediatric Critical Care physicians. Eight physicians have been granted privileges to independently select appropriate patients for ECLS; to oversee cannulation and decannulation procedures; and participate in daily and emergency management. During this funding year, all pediatric intensive care unit physicians and staff have been certified, and certification of all pediatric surgeons for Level 2 credentials has been completed.

a.5. Website

In addition to the clinical services provided by the Hanuola Center, a website has been developed to provide information to physicians, patients, families and the general public about ECMO and the Center. This website serves as a portal to the Hanuola ECMO Training courses, training manual and lectures. During this funding period, the website has been updated with staff list and contact information and Hanuola Training Course lectures. The transfer of the website administration to Kapi'olani is in process.

b. Conduct ongoing training, including didactic, wet labs, and animal labs based on well-established models.

During this funding period, quarterly refreshers, 4 hours each, to maintain ECMO competency for nurses, respiratory therapists and other ancillary staff members who have already completed the ECMO training course have been completed. Dates of the courses were on 29 September 2009, 2 November 2009 and 3 November 2009. A total of 48 participants completed competency review. A second ECMO training course was completed on 14 and 15 October 2009. Students included 24 participants; five of these participants were Adult Intensive Care RNs attending from Kaiser.

An animal training lab was held on October 15, 2009 for 12 participants for clinical training. Another animal training lab was held on 12 May 2010, again for 12 participants for clinical training. Training labs emphasize routine and emergent clinical skills with emphasis on communication. Participants include physicians, nurses, respiratory specialists and perfusionists. Outline objectives and specific curriculum have been completed for future ECMO Training

Courses and clinical lab training. TAMC Lab technicians are now able to operate ECMO system independently without perfusion support.

c. Conduct ongoing evaluation of clinical results against national benchmarks using established methodology.

The Extracorporeal Life Support Organization (ELSO) was established in 1989. The organization oversees and maintains the registry, promotes education and training materials in support of ECLS, and stimulates ongoing research (ELSO, 2005). One of the major functions of the ELSO is to maintain a Registry comprised of all known cases in which ECLS was performed (ELSO 2008). Aggregate data serves as national benchmarks and are evaluated to enhance extracorporeal support technology and the technique of ECLS.

The Hanuola ECMO Center has continued to submit detailed data to the ELSO registry through the data forms (See Appendix A.9).

d. Name and convene a National Advisory Board for Center review as part of an annual review meeting.

As part of the Hanuola Center, a National Advisory Board was selected. The current membership includes:

- Devn Cornish, MD – Vice Chairman of Faculty Development in Pediatrics, Emory University Medical School
- Denise Suttner, MD – Director, San Diego Regional ECMO Program.
- John Lin, MD – Pediatric Intensivist, Brooke Army Medical Center
- Michael Heard, RN –Egleston Children’s Hospital at Emory University
- William Harris, CCP – Ochsner Clinic, New Orleans
- Melissa McNeil, MD – Education Advisor, University of Pittsburg Medical Center
- Donald McCurnin, MD (*new*) – ECMO Program Director , University of Texas Southwestern Medical Center

For this reporting year, we have used the advisory committee for their expert consultation on a case by case basis. At the end of this reporting period, the Advisory board has been closed out. As is standard practice in the ELSO community, Hanuola will seek expert consultation from established ECMO centers and ELSO community experts via personal contact and the ECLS network, as needed on a case by case basis.

Task 2. To conduct basic science research to advance scientific knowledge in ECLS.

a. Renovate animal operating suite, to be scheduled around training and research

A dedicated animal operating suite at Tripler Army Medical Center Department of Clinical Investigation for ECMO research studies has been established. An ECMO System is made available to University of Hawaii Clinical Training Wet Labs and the Pediatric ECMO Hanuola Center at Kapiolani Medical Center for Women and Children on an as needed basis.

b. Conduct Center's first basic science research protocol after appropriate IRB approvals

The research project of putting the septic shock hypotensive pigs on ECMO and examining blood flow distribution to different organ beds is currently in the data analysis phase. All experiments have been completed and data is currently being analyzed and manuscripts are being drafted.

The specific aims of the study are being addressed as follows:

Aim 1: To characterize the cardiovascular and endocrine responses to ECMO after establishment of endotoxin-induced septic shock

In this study we tested the hypothesis that ECMO is an effective therapy for tissue preservation and maintenance of organ function in a porcine model of endotoxin-induced septic shock. Endotoxic shock was induced, and hormonal and physiologic parameters prior to ECMO and during ECMO therapy were compared. The original objectives of this study have been addressed and preliminary analysis suggests that this project may yield clinically relevant data that supports clinical guidelines for the use of Extracorporeal Membrane Oxygenation in the treatment of septic shock.

Aim 2: To compare ECMO delivery effectiveness of blood substitutes versus donor whole blood, on redistribution of perfusion to vital organs and tissue preservation in the face of endotoxin-induced septic shock

In the initial proposal, we had wanted to examine some of the side effects of the use of blood substitutes such as hemodilution and methemoglobinemia, and whether such conditions during septic shock, when the body is already compromised and struggling to maintain vital organ perfusion, can be tolerated. However, we were unable to obtain a source of artificial oxygen carrier (AOC), as vendors of such products had gone into bankruptcy, and so AOCs were no longer on the market. Thus we had to drop this part of the project. This part of the project was instead replaced by a more in depth look at the effect of ECMO on cardiovascular regulating hormones and the outcomes of shifts in microcirculatory flows as described above.

Aim 3: To evaluate whether ECMO prevents multi-system organ failure in septic shock, by examining organ function of the lungs and the kidneys, the organs most likely to fail in sepsis.

Based on the dilutional effect of ECMO on circulating hormone levels, we hypothesized that ECMO will not restore urine output in endotoxic shock despite cardiac stabilization and

maintenance of blood flow to the kidneys, as ECMO simultaneously reduces endogenous vasopressin levels which are needed to modulate local perfusion pressure and renal filtration. Preliminary results indicate that ECMO may interfere with the autoregulation ability of the kidneys to provide adequate pressure to restore filtration and urine flow in endotoxic shock.

Task 3. To develop manikin-based simulation training for the ECLS training curriculum, as a supplement to traditional ECLS training.

a. Develop simulation software and curriculum in conjunction with the infant patient simulator to serve as training adjuncts to animal and wet-lab training.

a.1. Hanuola ECMO Training Course

The Hanuola Center has completed the *Hanuola ECMO Training Course*; a comprehensive, traditional classroom-based ECMO training course for physicians, nurses, respiratory therapists, perfusionists or other health care professionals interested in understanding the concepts of extracorporeal membrane oxygenation. To provide an easily accessible web-based platform to improve pediatric care, the course has been converted to an online format which is available on the Center's training website. Competency learning modules have been developed to maintain ECMO competency for nurses, respiratory therapists and physicians who have already completed the ECMO training course. On 11 and 12 May 2010, an ECMO training course was held using the web-based curriculum and high fidelity manikin simulation. And again on 26 and 27 July 2010, a perfusion competency course using the same format was completed.

a.2. Critical Care Curriculum for Austere Environments

The Center has completed the *Pediatric Critical Care Curriculum for Austere Environments* that integrates manikin-based simulation. This curriculum provides as an online resource for multiple levels of health care providers without specific specialty training in the care of critically ill pediatric patients.

b. Evaluate the simulation curriculum.

Assessment and Intervention for Pediatric Patients in Emergency Situations

To evaluate the simulation curriculum, the Center developed the *Assessment and Intervention for Pediatric Patients in Emergency Situations* simulation-based training curriculum. Topics covered include pediatric airway anatomy and physiology, recognition of the pediatric patient in respiratory distress and respiratory failure, and shock. Neurologic emergencies and treatment options in pediatric patients are also discussed.

Thus far we have 22 participants that have completed the evaluation, with an additional three more participants lined up for the study. Data is currently being examined for integrity and preparation for data analysis. See Figures 1 and 2 below for the manikin study setup.



Figure 1 – Manikin Setup



Figure 2 – Manikin Interaction

Task 4. To develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.

ECMOjo scenario-based curriculum evaluation

Validation of ECMOjo has been completed at various ECMO Training Centers across the United States. Centers include: Rady Children's Hospital, San Diego, Children's National Medical Center, University of Pittsburgh Medical Center, Wilford Hall Medical Center, Arkansas Children's Hospital, Children's Healthcare of Atlanta, University of Iowa, Mayo Clinic, Lutheran General, and Children's Hospital of Philadelphia. A total of 51 medical professionals were enrolled to participate in an ECMO skills acquisition study. Subjects were randomized into two groups, one group doing conventional classroom learning and the other training on ECMOjo over the same period. Both groups were assessed using three wet-lab scenarios after their training, with wet-lab results compared between groups. Data has been collected and results of the study are currently being analyzed. Figures 3 and 4 display screenshots of the current version of ECMOjo.

User-based evaluations were also conducted to obtain feedback on the fidelity of the system. See Appendix B.1 for example of feedback.

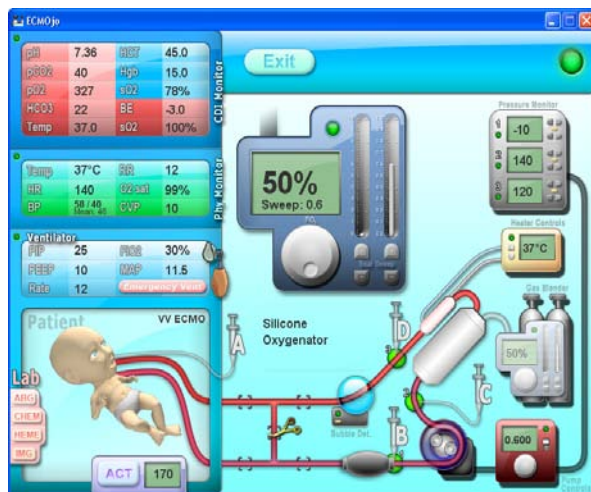


Figure 3 - Interactive GUI screen



Figure 4 – Scenario Selection Screen

Key Research Accomplishments

Task 1. To establish a new Hawaii-Pacific Rim extracorporeal life support (ECLS) Center, which provides advanced levels of care to Pediatric patients with life-threatening cardiorespiratory failure; to evaluate the Center's effectiveness in attaining clinical results that meet national ECLS benchmarks.

- Training manual developed for Hanuola ECMO Center. Ongoing revisions are being made to the original Training Manual developed in 2007. Hardcopy and electronic versions are available.
- ECMO Training Course—the course is ongoing to provide review and maintenance of skills.
- Hanuola ECMO Transport system has been designed and has obtained FAA certification

Task 2. To conduct basic science research to advance scientific knowledge in ECLS.

- Animal model for ECMO treatment of bacterial endotoxin-induced catecholamine-resistant vasodilatory septic shock has been developed.
- Using a piglet model of vasodilatory endotoxin-induced septic shock, we have characterized the cardiovascular and endocrine responses to ECMO.

Task 3. To develop manikin-based simulation training for the ECLS training curriculum, as a supplement to traditional ECLS training.

- Web platform has been created and course content has been loaded
- The following website contains the online learning portion and related quizzes
<http://www.tri.jabsom.hawaii.edu/manikinstudy/login.html>
- The following website contains the simulation portion and related quizzes for the study
http://simtiki.simmedical.com/apps/courses/courseview.asp?course_id=6277
- Evaluation of the simulation curriculum, *Assessment and Intervention for Pediatric Patients in Emergency Situations*, is under way.

Task 4. To develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.

- The development of ECMOjo, a simulator and trainer for extracorporeal membrane oxygenation, has been completed.
- Validation study has been completed.
- Project software has been updated at SourceForge.net and is available as Open Source for ECMO practitioners worldwide.
<http://ecmojo.sourceforge.net>

Reportable Outcomes

- Abstracts, Presentations, Publications:
 - Ogino MT. ECMO Training Using Simulation. The 26th Annual Children's National Medical Center Symposium on ECMO & Advanced Therapies for Respiratory Failure, Keystone CO. Feb 2010.
 - Tanaka LY, Aschwanden C, Burgess L, Ogino MT. Computer-Based Simulation for Extracorporeal Membrane Oxygenation (ECMO) Skills Training. International Medical Simulation in Healthcare, Phoenix, AZ. Jan 2010. 5
 - Tabak BD, Tanaka LY, Mahnke CB, Elliott CL, Costales KG, Ogino MT. Echo for ECMO: Guiding Avalon Catheter Placement for VV ECMO. ECMO and the Advanced Therapies for Respiratory Failure, Keystone, CO. Feb 2010. (platform presentation)
 - Costales KC, Tanaka TY, Kilcommons MM, Takenaka WS, Sommer-Candelario SA, Ogino MT. Santa's Got a Brand New Sled. ECMO and the Advanced Therapies for Respiratory Failure, Keystone, CO. Feb 2010. (platform presentation) Appendix A.1.
 - Costales KC, Kilcommons MM, Takenaka WS, Ogino MT. ECMO Transport Across the Pacific: A Case Report. Poster presentation. ECMO and the Advanced Therapies for Respiratory Failure, Keystone, CO. Feb 2010. Appendix A.2
 - Tabak BD, Tanaka LY, Mannke CB, Elliott CL, Costales KC, Ogino MT. Echocardiographic Evaluation of the Avalon Elite Bi-caval Dual Lumen Catheter in Neonatal and Pediatric VV ECMO. ECMO and the Advanced Therapies for Respiratory Failure, Keystone, CO. Feb 2010.
 - L. Y. Tanaka, M. T. Ogino, C. Aschwanden, K. G. Costales and L. Burgess. Computer-Based Simulation Application for Extracorporeal Membrane Oxygenation (ECMO) Skills Training Poster presentation. 10th Annual International Meeting on Simulation in Healthcare (IMSH), Phoenix, Arizona, January 23-27, 2010
 - Uyehara CFT, Batts SG, Kinnison MW, McEntire SP, Sato AK, Ichimura WM, Hashiro GM, and Hernandez CA. Vasopressin Regulation During Extracorporeal Membrane Oxygenation (ECMO) in a Pig Model of Septic Shock. FASEB J. 23: 605.1, 2009.
 - Cardiovascular Hormonal Responses and Microcirculatory Flow During ECMO Treatment in a Piglet Model of Endotoxic Shock. Catherine F T Uyehara, Sherreen G Batts, Thornton S Mu, Sarah L Lentz-Kapua, Martin W Kinnison, Aileen K Sato, Wayne M Ichimura, and Claudia A Hernandez. Presented at The Department of Defense Peer Reviewed Medical Research Program Military Health Research Forum, Kansas City Missouri, August 2009. (Hosted by The U.S. Army Medical Research and Materiel Command.)
 - The animal study task has been successfully used to provide research opportunities for military Graduate Medical Education trainees, and to develop research interests of residents and staff of Tripler Army Medical Center's Department of Surgery. Results were presented by military GME trainees at the following:
 - Podium presentation at AAP national convention Perinatal Section Washington, D.C. Platform session October 2009

- Podium presentation at COMPRA, Bastrop, Texas November 2009
 - Podium presentation at 11th Annual James W. Bass Research Symposium, 20 May 2010, Tripler AMC, HI.
 - Podium presentation at 12th Annual James W. Bass Research Symposium, 19 May 2010, Tripler AMC, HI.
 - Podium presentation at 29th Annual Conference of Military Perinatal Research, 6 Nov 2010, Austin, TX.
- ECMO Physician Credentialing
 - All PICU physician staff have been certified.
 - Certification all Pediatric surgeons for Level 2 credentials has been completed.
- Meetings held on 14-16 December 2009 with UPMC and Hawaii ECMO team to discuss program progress and future. The following are presentation/discussions that were held. QPR 14
 - *Appendix A.3* – History of the Hawaii ECMO project - Overview
 - *Appendix A.4* – Description of the ECMO Sled 2
 - *Appendix A.5* – Hanuola Website Development Overview
 - *Appendix A.6* – Discussion on ELSO database comparison with Hanuola data
 - *Appendix A.7* – Biotronics Collaboration Overview
- Data submitted to ELSO registry
- The animal model for endotoxin-induced septic shock using a pediatric piglet model has been completed and results are currently being analyzed.
- Design and engineering of the ECMO Transport Sled is complete. Construction is pending.
- Review article published in AmSECT Today, Sept/Oct edition, Appendix A.8, pg 7.

Conclusions

The Hanuola (ECMO) Center has been successfully established at Kapi'olani Medical Center for Women and Children. The following are a summary of activities thus far:

- Policies and procedures with other supporting clinical departments have been integrated into the program.
- ECMO patients are currently being treated and consulted, 21 consulted and 8 treated during this reporting period.
- An ECMO transport system has been certified and will be available for use for the Center into the future.
- Animal model for ECMO treatment of bacterial endotoxin-induced catecholamine-resistant vasodilatory septic shock has been developed.
- Web platform has been created for the *Hanuola ECMO Training Course*; a comprehensive, traditional classroom-based ECMO training course for physicians, nurses, respiratory therapists, perfusionists or other health care professionals interested in understanding the concepts of extracorporeal membrane oxygenation. Also, the *Critical Care Curriculum for Austere Environments* course is also available on the website.
- ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data has been developed and made available online for ECMO practitioners worldwide.

The establishment of the Hanuola Center has significantly improved the level of care provided to DOD dependents in the Pacific region and to all children in the State of Hawaii. The Hanuola Center is now providing state-of-the-art critical care support for patients and state-of-the-art educational opportunities to pediatric providers, which is bringing the standard of care for pediatric patients in Hawaii to an equal footing with patients on the U.S. mainland.

Results from the animal studies indicate that ECMO may help reduce morbidity and mortality from endotoxin-induced shock by providing cardio-respiratory support. Septic shock is a high-risk disease of infection seen in all military hospitals. Susceptibility of battlefield wounds to infections and possibilities of soldier exposure to biological warfare agents makes the treatment of septic shock a significant “military relevant disease management” concern. Guidelines for perfusion parameters and hormone replacement therapy provided by this study help clarify the role for ECMO in the treatment of septic shock in military clinical practice.

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Appendices

- A. Task 1.a. Establish ECLS Center at Kapi'olani Medical Center for Women and Children using well-established clinical and referral guidelines, and training curricula**
- Appendix A.1. Santa's Got a Brand New Sled – presentation
 - Appendix A.2. ECMO Transport Across the Pacific: A Case Report – poster presentation
 - Appendix A.3. History of the Hawaii ECMO project – Overview
 - Appendix A.4. Description of the ECMO Sled 2
 - Appendix A.5. Hanuola Website Development Overview
 - Appendix A.6. Discussion on ELSO database comparison with Hanuola data
 - Appendix A.7. Biotronics Collaboration Overview
 - Appendix A.8. Review article published in AmSECT Today, Sept/Oct edition (see pg 7).
 - Appendix A.9. ELSO Results, Hanuola Center
- B. Task 4. Develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.**
- Appendix B.1. ECMOjo Evaluation 13 August 2010

Appendix A.1.

Hanuola ECMO Transport Project



Senator Daniel Inouye

“Santa’s Got A Brand New Sled”

Costales KG, Takenaka WS, Kilcommons MM, Ogino MT

Hanuola ECMO Program of Hawaii
Kapiolani Medical Center for Women and Children, Honolulu HI

Kristen.costales@kapiolani.org

10 ETS Design Essentials

1. Must accommodate all sizes of patients
2. Must fit into all modes of transportation without modification
3. ECMO circuit must be protected yet accessible
4. All equipment, tubing, cables, tanks, and medical lines must fit within the footprint of the ETS platform
5. Must have UPS available for all vital equipment

A Year of Education

- Kapiolani ETS team meetings
- Consultations
 - University of Pittsburgh
 - Children’s Hospital of Pittsburgh
- Site visits
 - Royal Children’s Hospital, Melbourne
 - Wilford Hall Medical Center, San Antonio
 - Arkansas Children’s Hospital, Little Rock
 - British Columbia Children’s Hospital, Vancouver

AirMed International

Birmingham, Alabama

- Global medical transport company
- Kapiolani’s patient transport contractor
- King Air, Hawker, Learjet, and Beechjet aircraft
- Site visit and initial proposal September 2008
 - Project manager assigned
 - Equipment identification and transfer
 - Elliott Aviation partnership



10 ETS Design Essentials

6. Must have blended gases on board
7. Must have ability to maintain desired patient temperature
8. All lines must be organized, secured, identified, protected, and easily accessible
9. Equipment on ETS must be located in relation to appropriate team member’s position in flight
10. ETS must be designed, engineered, and tested to meet FAA guidelines, standards

Elliott Aviation

Moline, Illinois

- Aviation products and services
- Design, engineering, build, test facility
- FAA liaison
- Site visit January 2009
 - Assembly of team members
 - First mock-up of ETS project
 - Identification of structure, equipment location, power, gas, weight
 - FAA requirements



AirMed Control Center Birmingham Alabama



Design and engineering team at work May 2009



Elliott Aviation Moline Illinois



Hawker fit test May 2009



Hanuola team August 2009



Side by side with aircraft stretcher



Design

- Total weight fully loaded 250 lbs.
- Patient weight up to 200 lbs. on current medical base
- Engineered for weight, balance and structural integrity within the frame, medical base
- Recessed low profile handles, 4 sides
- LifePort footprint

Hanuola ECMO Transport System

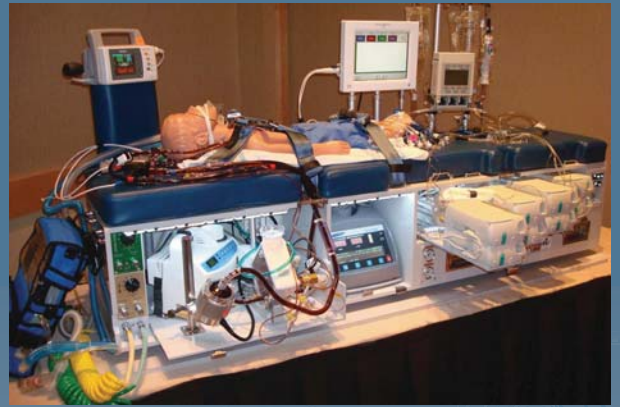


ETS Platform Aluminum honeycomb frame





Levitronix/Maquet, heater, blender



Slide out trays for accessibility

Electrical bus



Power

- 8.5 amp inverter in aircraft and ambulance
- Power cords routed through relay to two external AC cords
 - RED - Pump, heater, M3
 - BLACK - Monitors, IV and syringe pumps
- Alternating syringe pump power switch
- Internal battery capacity for most equipment
- Power protocol to avoid overload
- UPS peripheral for vital equipment

GeoData Systems UPS

- Dual NiMH batteries
- Lightweight, 52 lbs.
- Temperature resistant
- Dual 110 vAC, 375 watts output
- 43 amp/hr capacity
- Rolling Pelican™ case



Syringe pump power toggle, lights

Gas system



Gas system

- Two aluminum E cylinders – 1 air, 1 oxygen
 - Lightweight
 - 700 gaseous liters each
 - Support for transition periods
- Internal routing of air/oxygen lines to blender and exterior connection panel
- Exterior gas connection panel
 - Quick connects for transfer to ambulance or aircraft tanks
 - Air and Oxygen flow meters



And away we go....

Substantiation Process

- **STC (Supplemental Type Certificate)**
 - Engineering package received by FAA
 - FAA issues certificate 8110-3 for airworthiness Beechjet, Hawker, King Air, Learjet
 - Completed ETS with all equipment must pass EMR/EMI testing for FAA
 - STC issued
 - Estimated completion March 2010



ECMO Transport Across the Pacific: A Case Report



K. G. Costales^{1,2}, M. M. Kilcommons^{1,2}, L. Y. Tanaka^{1,2}, W. S. Takenaka¹, S. A. Sommer-Candelario¹, M. T. Ogino^{1,2,3}

¹ Kapiolani Medical Center for Women & Children; Honolulu, Hawaii | ² Hanuola ECMO Program; Honolulu, Hawaii | ³ University of Pennsylvania School of Medicine; Philadelphia, Pennsylvania

Introduction:

Hawaii is the most geographically isolated land mass on Earth. This distinction poses many problems for critically ill children in need of advanced medical care available in specialized hospitals. Patients who require ECMO for complex congenital cardiac defects are a prime example. The mission of the Hanuola ECMO Program of Hawaii is to bring ECMO to pediatric patients in the Pacific Basin and to develop an ECMO transport program, which includes the design and production of a specialized ECLS transport system. Before this system was completed, we were presented with a patient who required urgent transport, on ECMO, from Hawaii to San Diego for congenital cardiac surgery. We describe the first civilian air ECMO transport of a patient across the Pacific Ocean, from Honolulu, Hawaii to San Diego, California.

Case Report:

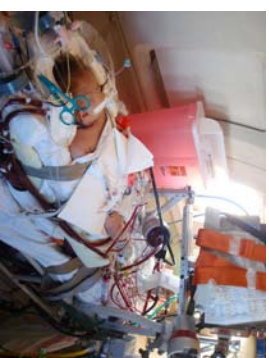
A 2 month-old, 4 kilogram male presented to the PICU with an undiagnosed supracardiac total anomalous pulmonary venous return (TAPVR). While arrangements were being made for transport to the mainland U.S., the patient developed ventricular tachycardia, renal failure, and acidosis. The patient's dysrhythmia stabilized on lidocaine and amiodarone, however, worsening cardiac output required veno-arterial ECMO support. A team of critical care nurses, perfusionists, respiratory therapists, physicians, BioMed staff was convened to plan the development of a safe and practical transport sled. Aimed International provided the air medical transportation for this transpacific transfer. A Hawker 800 aircraft was used to transport the 5 member team. The total transport time from door-to-door was 8 hours, with a flight time of 5 hours 37 minutes. The patient underwent successful surgical correction the next day and went on to recovery.

Conclusions:

ECMO transport over the open ocean presents many interesting challenges for both the medical team and the transport modality. Prolonged isolation from medical facilities, power limitations, and aircraft space limitations are the most formidable. In addition, long flight times carry an increased risk for multiple patient interventions, equipment malfunction, and medical supply depletion. A high degree of coordination between the various entities involved is essential to avoid critical consequences. We describe our experience with these challenges in our first transpacific air ECMO transport.



Hawaii's Geographical Isolation:
Flight time 5 hours 37 minutes



Patient and Circuit: limited supply storage, seating positions for personnel dictate roles in patient care



Equipment Issues: narrow aisle, low fuselage clearance, gas flow



Tarmac Issues: visibility at night, weather protection

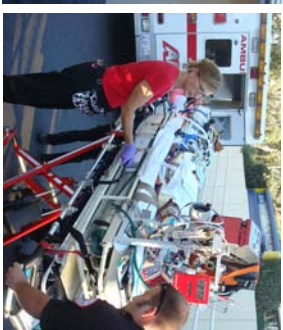
| Powered Equipment | Weight lbs | Current Draw (amps) | Battery Time (mins) |
|----------------------------------|---------------|------------------------|------------------------|
| Maquet Rotaflow System | 31 | 2 | 90 |
| Maquet Rotaflow Drive Unit | 7 | na | na |
| Maquet Rotaflow Heat Exchanger | 4.6 | na | na |
| Maquet Rotaflow Prime Circuit | 14.5 | na | na |
| Maquet Rotaflow Prime Pump | 14.5 | na | na |
| Pulmonary Spont Battery Peak LTV | 4.5 | na | 300 |
| Prolog Monitor | 6.25 | 0.75 | 300 |
| CS2 Heater | 11.4 | 1.75 | na |
| Aera MedSystem II Triple Pump | 5.1 | 0.05 | 360 |
| Aera MedSystem II Triple Pump | 5.1 | 0.05 | 360 |
| USC Syringe Pump (9) | 3.8 | 0.7 | 360 |
| USC Syringe Pump (10) | 3.8 | 0.7 | 360 |

| Other Equipment | Weight lbs | Current Draw (amps) | Battery Time (mins) |
|--------------------------------|---------------|------------------------|------------------------|
| Quadrox D Oxygenator | na | na | na |
| Isat Analyzers (2) | na | na | na |
| Medtronic Pressure Display Box | na | na | na |
| Medtronic Pressure Display Box | na | na | na |
| Medtronic Pressure Display Box | na | na | na |
| Medtronic Pressure Display Box | na | na | na |
| Medtronic Pressure Display Box | na | na | na |
| Medtronic Pressure Display Box | na | na | na |
| Medtronic Pressure Display Box | na | na | na |
| Medtronic Pressure Display Box | na | na | na |

Ambulance Inverter: 8.5 Amps
Aimed Hawker Jet two Inverters: 8.5 Amps



Ambulance Considerations:
Working inverter, air/oxygen, door height, gurney position, skilled personnel



Aimed International and the Hawker 800:
Door to door coordination of aircraft, pilots, team

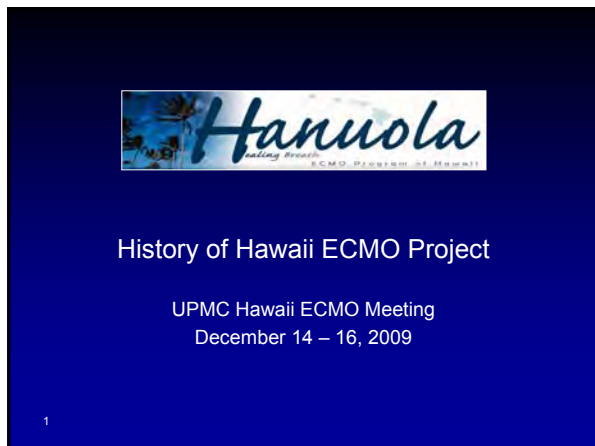


Aircraft Logistics: small aircraft door, power limitations



Space Limitations: physician, perfusionist, ECMO nurse, transport nurse, RT/flight safety officer

Appendix A.3



ECMO referrals to the mainland

- Record review 24 ECMO referrals
 - 24 ECMO referrals
 - 97 ECMO eligible infants (1994-2001)
- Survival
 - 65% in a subgroup of babies who were transferred to the mainland for ECMO
 - 80% to 95% at an ECMO center
- Morbidity
 - Non ECMO survivors – higher rates of pulmonary bleeding, IVH, oxygen at discharge

3

Hero

- TJ (2003)
 - “Persistent Pulmonary Hypertension of the Newborn”
 - Limited blood flow to the lungs with right heart failure
 - Mainland ECMO center called
 - Air ambulance not available for 24 hours
 - Wilford Hall ECMO team contacted. USAF aircraft on east coast.

4





Hero

"TJ"
and
his family



Dan Inouye

U.S. SENATOR FROM HAWAII



Extra Corporal Membrane Oxygenation at Tripler *\$6 million*

This new project would establish a state of the art lifesaving technique often used on newborns, young children, and, at times, adults whose heart or lungs are failing, as a partnership of Tripler, Kapiolani Medical Center for Women and Children and Kaiser Permanente. Hawaii is presently without this capability, requiring medevacs of patients to mainland facilities.

FOR IMMEDIATE RELEASE

WASHINGTON — U.S. Senator Daniel K. Inouye announced tonight that a bill with nearly \$496.7 million in defense-related spending for Hawaii has been approved by Congress. The bill will now be sent to the White House for the President's signature.



Pacific Pediatric Advanced Care Initiative

1. Establish an ECMO center
2. Conduct basic science ECMO research
3. Develop simulation training for ECMO curriculum

13

Hero



14



Establish a Hawaii-Pacific Rim ECMO center



As of July 1, 2007

- Establish ECMO center to support Department of Defense (DOD) and civilian neonatal and pediatric populations
- Develop second DOD ECMO transport program

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Hanuola

Physician Support
 Kapiolani Medical Specialists
 Kaiser Permanente
 Tripler Army Medical Center

Perfusion Support
 Biotronics, UPMC

19

Hanuola Advisory Board

| | |
|--|--|
| <p>Devn Cornish, MD Professor and Vice Chair, Faculty Development Emory University, Department of Pediatrics</p> <p>William Harris, CCP Assistant Director, Extracorporeal Technology Chief Perfusionist Ochsner Foundation Clinic</p> <p>Micheal Heard, RN Coordinator, ECMO and Advanced Technologies Children's Healthcare of Atlanta</p> <p>John Lin, MD Director, Pediatric Critical Care USAF Wilford Hall Medical Center</p> | <p>Donald McCurnin, MD Professor, Department of Pediatrics Chief, Neonatology University of Texas Southwestern Medical Center</p> <p>Melissa McNeil, MD, MPH Associate Chief, Section of General Medicine Director, Comprehensive Women's Health Program University of Pittsburgh Medical Center</p> <p>Denise Suttner, MD Director, San Diego Regional ECMO Program Rady Children's Hospital and Health Center</p> |
|--|--|

20



21



22





Pacific Pediatric Advanced Care Initiative

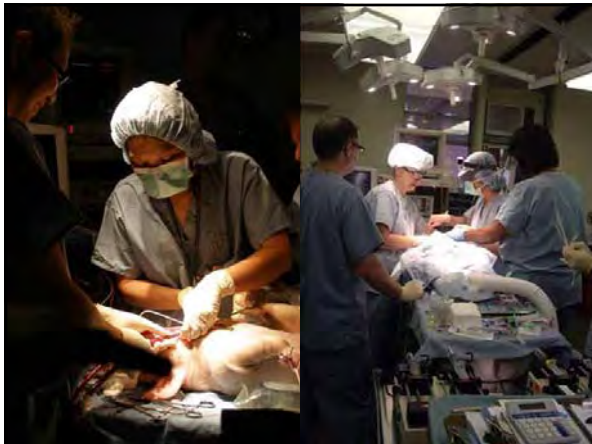
1. Establish an ECMO center
2. Conduct basic science ECMO research
3. Develop simulation training for ECMO curriculum

27

TAMC Department of Clinical Investigation



28



Pacific Pediatric Advanced Care Initiative

1. Establish an ECMO center
2. Conduct basic science ECMO research
3. Develop simulation training for ECMO curriculum

30



National and International Recognition

Extracorporeal Life Support Organization (ELSO)

- 2006, Atlanta: Hanuola
- 2008, San Diego: ECMOjo

Children's National Medical Center ECMO Conference, Keystone

- 2007: Simulation
- 2010: Simulation, ECMO Transport

Society for Simulation in Health Care

- 2010 IMSH: ECMOjo

32

National and International Recognition

ELSO

- Steering Committee Member, Extracorporeal Life Support Organization
- Co-editor, ELSO Training Manual

SEECMO

- 2010, Iowa City: Simulation

Other

- Royal Children's Hospital, Melbourne Australia

33

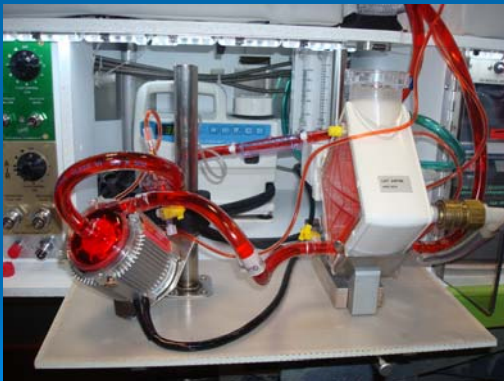
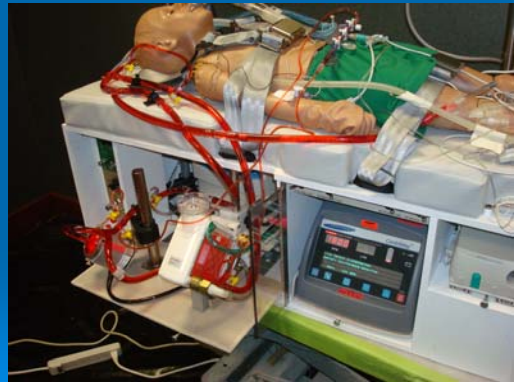
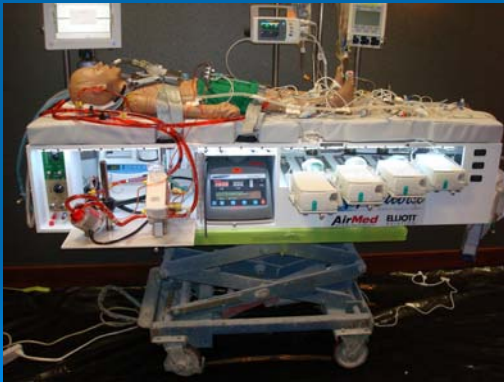
"We are in the business of hope"

34



Appendix A.4

Hanuola team
August 2009





Solutions

- Power
 - 8.5 amp inverter in aircraft and ambulance
 - Battery capacity for all vital equipment
 - UPS peripheral for equipment without batteries
 - Power cords routed through relay to two ETS AC cords
 - Develop power protocol to avoid overload

Solutions

- Gas
 - Two aluminum E cylinders – 1 air, 1 oxygen
 - Lightweight
 - 700 gaseous liters each
 - Support for transition periods
 - Oxygen shared with ventilator and blender
 - Built-in panel with gas connections
 - Quick connects for transfer to ambulance or aircraft tanks
 - Oxygen flow meter for hand bagging

Substantiation Process

- Elliott Aviation to begin build of ETS December 1, 2009
- Completion set for mid-January 2010
- Final drawings and data from engineer to be sent to FAA

Substantiation Process

➤ STC (Supplemental Type Certificate)

- Final engineering package received by FAA
- FAA issues certificate 8110-3 for aircraft category – first Beechjet, followed by Hawker, King Air, Learjet
- Completed ETS with all equipment must pass EMR/EMI testing for FAA
- STC issued, owned by Hanuola
- Estimated completion February/March 2010



Costs

➤ Engineering, Design, FAA Approval Process

- Funding: DoD grant

➤ Construction

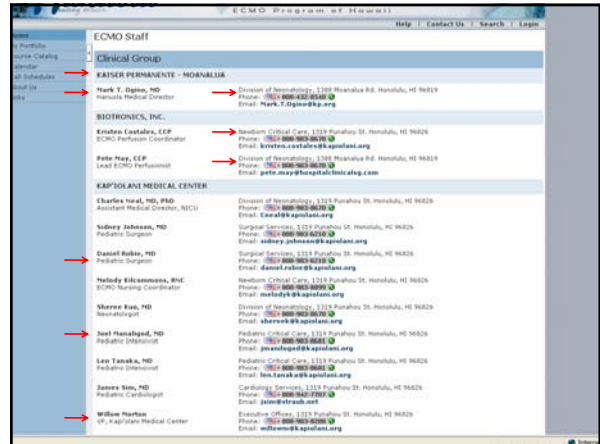
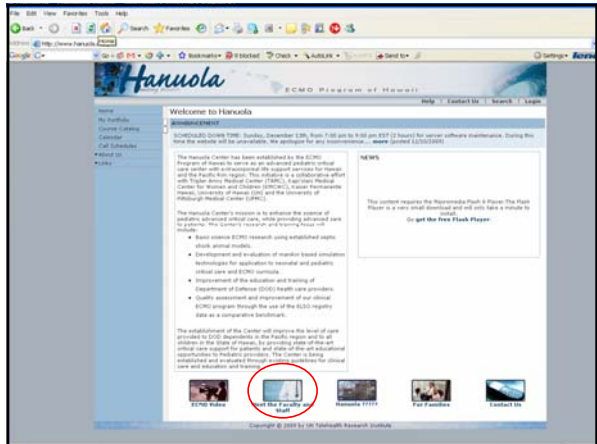
- ECMO Transport Platform \$118,000
- Spare Parts \$34,000
- Equipment \$212,000
- Additional aircraft STC \$5000 each
- Funding: Partial funding DoD Grant
External Funding Sources

Policy and Procedure

➤ Build off of existing KMCWC Transport Protocols

➤ Checklists completed

- Equipment
- Supplies
- Guidelines for preparation and execution
- Power and weight chart

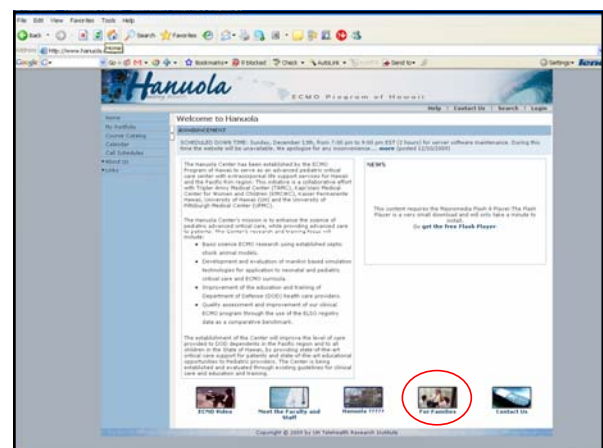
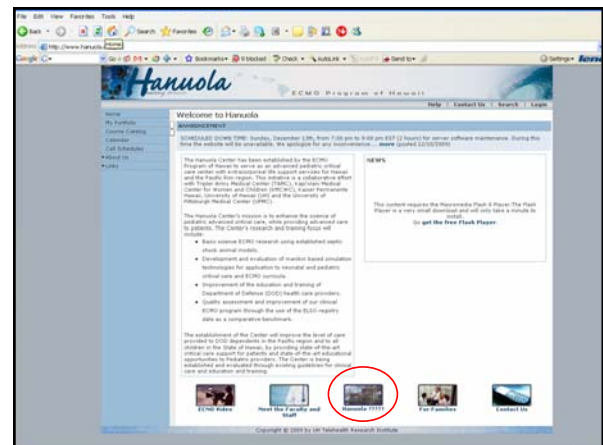


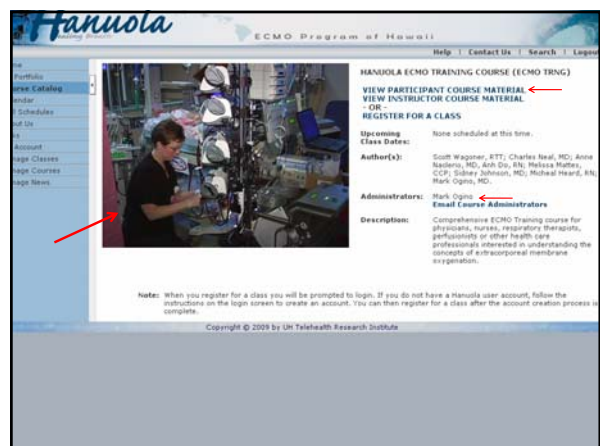
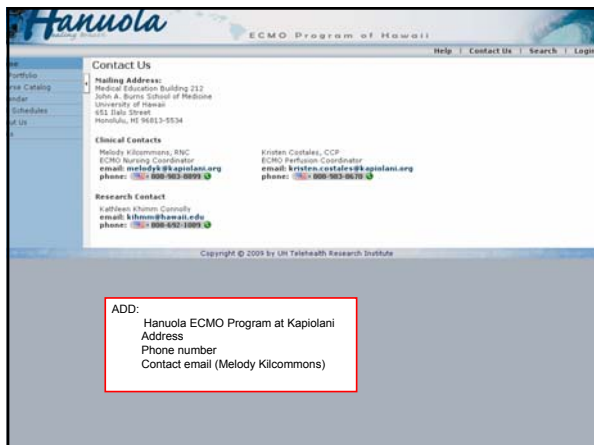
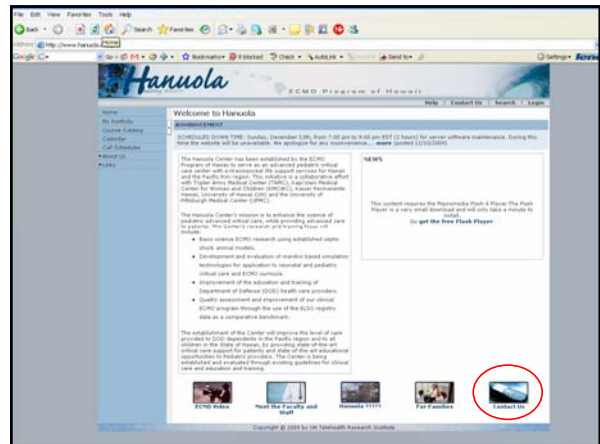
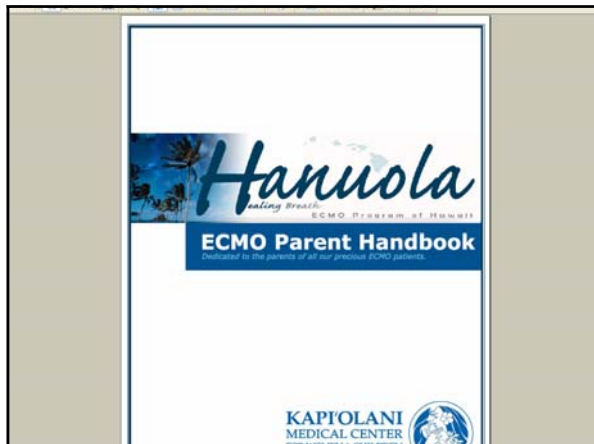
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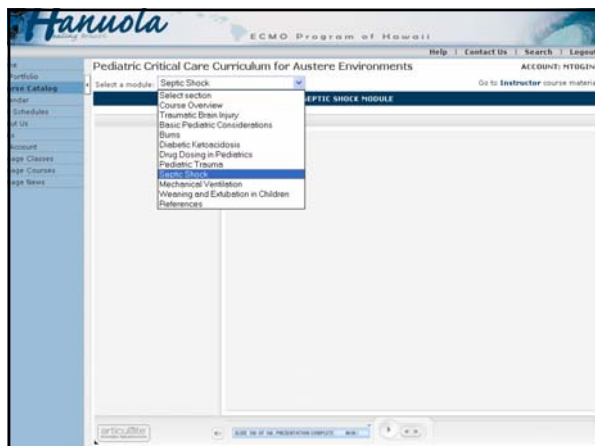
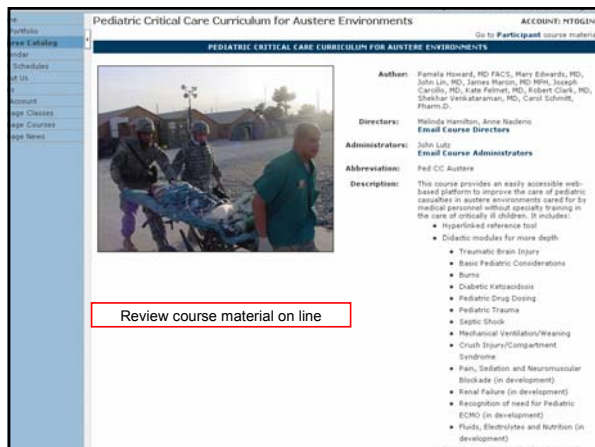
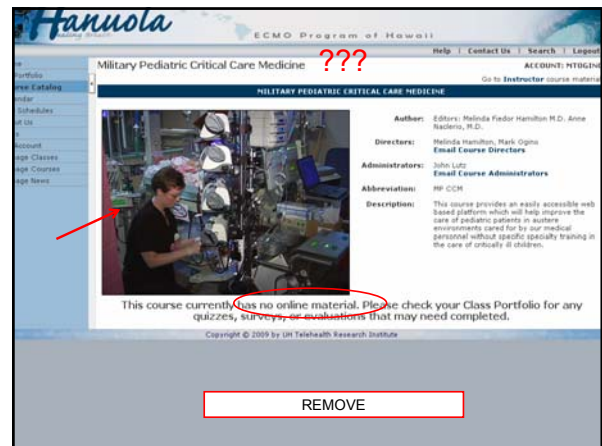
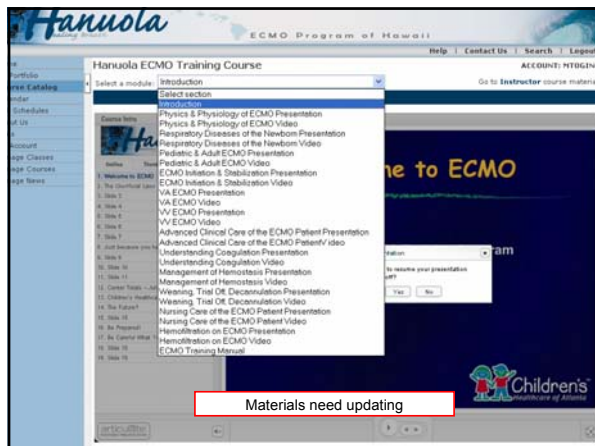
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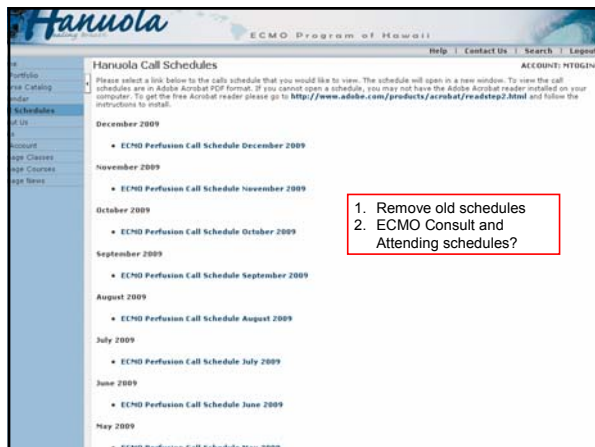
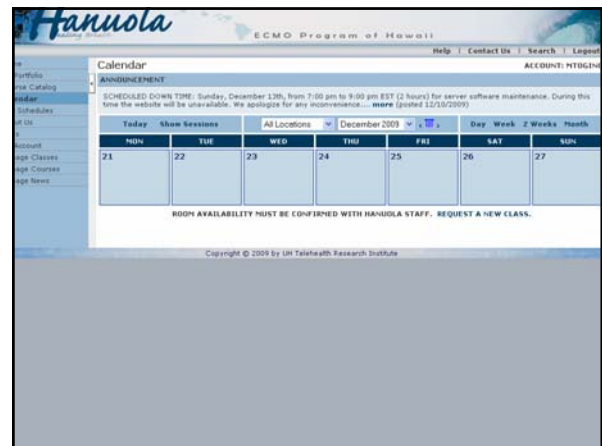
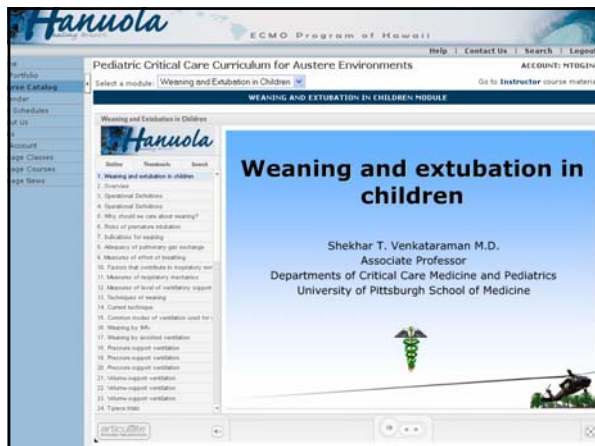
Additions

- Tyree, Puapong, Woo, Feng, Xonis, Oliveras, Kabbur, Level one ECMO
- David Palmer, Kent Kelly, Brad Kuch
- Link to Advisory Board Letter
- Group to UPMC
- Advisory Board
- Ogino @ CHOP









Long Term Plans

- Original platform for scheduling, but current use is informational
- Change platform for long term use and allows local updating
 - Transition over the next year
 - Where:
 - Kapiolani – NO, no outside access
 - TRI SimTiki – NO, domain issues
 - Hosting Company – YES, ask Christoph. Kap needs to support & maintain
 - Change platform to lower cost
 - Transfer domain from UPMC to Hawaii

Appendix A.6

Hanuola-ELSO Database Comparison

Hanuola Data July 2007 – November 2009
ELSO Data 2003-2008

Hanuola ECMO Patients July 2007 to November 2009

| | |
|----------------------------|-----------|
| Neonatal Respiratory | 8 |
| Neonatal Cardiac | 1 |
| Pediatric Respiratory | 4 |
| Pediatric Cardiac | 2 |
| Pediatric ECPR | 1 |
| Total ECMO Patients | 16 |

OVERALL OUTCOMES: Neonatal Respiratory ECLS

| | <u>Hanuola</u> | <u>ELSO Database</u> |
|------------------------------|----------------|----------------------|
| Total Number Patients | 8 | 4661 |
| Survived ECLS | 75% | 67% |
| Survived to discharge | 75% | * |

* 5 year data not available

OVERALL OUTCOMES: Neonatal Respiratory Runs By Diagnosis

| | | <u>Hanuola</u> | <u>ELSO Database</u> |
|---------------|---------------|----------------|----------------------|
| PPHN | # of patients | 2 | 848 |
| | % survived | 50% | 76% |
| CDH | # of patients | 1 | 1497 |
| | % survived | 100% | 45% |
| Sepsis | # of patients | 2 | 249 |
| | % survived | 50% | 71% |

OVERALL OUTCOMES: Neonatal Respiratory Runs By Diagnosis

| | | <u>Hanuola</u> | <u>ELSO Database</u> |
|------------|---------------|----------------|----------------------|
| MAS | # of patients | 3 | 1051 |
| | % survived | 100% | 92% |

Overall Outcomes: Neonatal Cardiac ECLS

| | <u>Hanuola</u> | <u>ELSO Database</u> |
|------------------------------|----------------|----------------------|
| Total Number Patients | 1 | 1779 |
| Survived ECLS | 100% | 39% |
| Survived to Discharge | 100% | * |

* 5 year data not available

OVERALL OUTCOMES:

Pediatric Respiratory ECLS

| | <u>Hanuola</u> | <u>ELSO Database</u> |
|-----------------------|----------------|----------------------|
| Total Number Patients | 4 | 4005 |
| Survived ECLS | 75% | 64% |
| Survived to discharge | 50% | * |

* 5 year data not available

OVERALL OUTCOMES:

Pediatric Respiratory Runs By Diagnosis

| | | <u>Hanuola</u> | <u>ELSO Database</u> |
|-----------------|---------------|----------------|----------------------|
| Viral Pneumonia | # of patients | 3 | 213 |
| | % survived | 67% | 68% |
| Other | # of patients | 1 | 775 |
| | % survived | 100% | 50% |

OVERALL OUTCOMES:

Pediatric Cardiac ECLS 31 days to < 1 year

| | <u>Hanuola</u> | <u>ELSO Database</u> |
|-----------------------|----------------|----------------------|
| Total Number Patients | 1 | 954 |
| Survived ECLS | 1/1 = 100% | 455/954 = 48% |
| Survived to Discharge | * | * |

* 5 year data not available/discharge status pending

OVERALL OUTCOMES:Cardiac ECLS: Congenital Diagnosis by Age Group
31 days to < 1 year

| | <u>Hanuola</u> | <u>ELSO Database</u> |
|-----------------------|----------------|----------------------|
| Other | 1 | 221 |
| Survived ECLS | 1/1 = 100% | 111/221 = 50% |
| Survived to Discharge | * | * |

* 5 year data not available

OVERALL OUTCOMES:

Pediatric Cardiac ECLS 1 year to <16 years

| | <u>Hanuola</u> | <u>ELSO Database</u> |
|-----------------------|----------------|----------------------|
| Total Number Patients | 1 | 806 |
| Survived ECLS | 1/1 = 100% | 451/806 = 56% |
| Survived to Discharge | 0/1 = 0% | * |

* 5 year data not available

OVERALL OUTCOMES:Cardiac ECLS: Congenital Diagnosis by Age Group
1 year to <16 years

| | <u>Hanuola</u> | <u>ELSO Database</u> |
|-----------------------|----------------|----------------------|
| HPLH | 1 | 38 |
| Survived ECLS | 1/1 = 100% | 19/38 = 50% |
| Survived to Discharge | 0/1 = 0% | * |

* 5 year data not available

OVERALL OUTCOMES:

Neonatal & Pediatric Cardiac ECLS: All Age Groups

| | <u>Hanuola</u> | <u>ELSO Database</u> |
|-----------------------|----------------|----------------------|
| Total Number Patients | 3 | 4186 |
| Survived ECLS | 3/3 = 100% | 44% |
| Survived to Discharge | *2/3 = 50% | * |

* 5 year data not available/discharge status pending

OVERALL OUTCOMES:

Pediatric ECPR

| | <u>Hanuola</u> | <u>ELSO Database</u> |
|-----------------------|----------------|----------------------|
| Total Number Patients | 1 | 832 |
| Survived ECLS | 0% | 52% |
| Survived to discharge | 0% | 39% |

* 5 year data not available

Total Referrals

| | <u>NICU</u> | <u>PICU</u> | <u>TOTAL</u> | <u>ECMO</u> |
|------|-------------|-------------|--------------|-------------|
| 2007 | 3 | 2 | 5 | 2 |
| 2008 | 9 | 10 | 19 | 4 |
| 2009 | 6 | 9 | 15 | 10 |

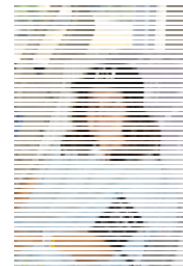
APRIL RUN



OCTOBER RUN



AUGUST RUN





Appendix A.7



BioTronics Collaboration

"Hanuola ECMO 2010 and Beyond"

David A. Palmer, Ed.D., CCP
Director, Perfusion Services

Hanuola and BioTronics

"Our common goals"

- BioTronics, Inc.
 - University of Pittsburgh Medical Center
 - Service lines
 - Personnel and activity
 - Our programs
 - Solutions



Our Community Presence


- 52,000 Employees
- \$7.5B in Assets
- \$7.7B in Revenue
- 20 Hospitals operating nearly 4200 beds
- 43 Regional Cancer Locations
- More than 400 Service Locations
- 188,000 admissions
- 1.4M lives covered in Insurance Division products
- \$169M Charity Care
- \$99M Community Health Programs and Donations
- \$250M Support for Research and Education
- \$24M Taxes and Voluntary Contributions

BioTronics Service Lines

**BioTronics, Inc.
Clinical Services**


Perfusion

Cardiopulmonary bypass
Long term cardiopulmonary support
Perioperative blood management
Chemo-perfusion
Equipment & supply management
Consultation




Biomedical

Biomedical equipment management
Information technology
Data Management



Vital Engineering

Cardiac assist device management
Personnel training and competence
Program implementation



Overview

- 65 personnel: certified perfusionists and autotransfusion specialists
- Average of 10+ years experience
- Service area:
 - Western Pennsylvania
 - Eastern Ohio
 - Northern West Virginia
 - Baltimore Washington area
 - Western Maryland area



Perfusion Activity

- 5,000+ open-heart procedures
- 7,500+ autotransfusions
- Platelet gel therapy
- 150+ chemoperfusion procedures
- 150+ long term ECMO/VAD supports
- 625+ intra-aortic balloon
- Transport services
- Perioperative services
- Consultation services



Our Programs

Heart

UPMC Presbyterian
UPMC Shadyside
UPMC Passavant
UPMC Mercy
Jefferson, PA
DuBois, PA
Westmoreland, PA
Good Samaritan, PA
Butler, PA
Pittsburgh VA, PA
Washington, PA
Affinity, OH
Forum Northside, OH
Forum Trumbull, OH
Trinity, WV
Honolulu, Hawaii

Chemo Perfusion

UPMC Presbyterian
UPMC Passavant
UPMC Shadyside
UPMC Magee
Mercy, MD

Perioperative

UPMC Southside
UPMC Greenville
UPMC Shenango
UPMC St. Margaret
UPMC Hammarville
UPMC McKeesport
UPMC Magee
UPMC Northwest
Mon General, PA
Ohio Valley, PA
Warren, PA
Somerset, PA
Jameson, PA
Mercy Jeannette, PA
Excelsa Latrobe, PA
Excelsa Frick, PA
Indiana Regional, PA
Charles Cole, PA

Perioperative

Ashtabula, OH
UHS Brown, OH.
Salem, OH
East Ohio, OH
Ohio Valley, WV
United Health, WV
Davis Memorial, WV
VA, Clarksburg, WV
Weston, WV
Reynolds, WV
Garrett, MD
Doctors, MD
South Maryland, MD
Franklin Square, MD
Sibley, DC
Potomac, VA

Perfusion Services

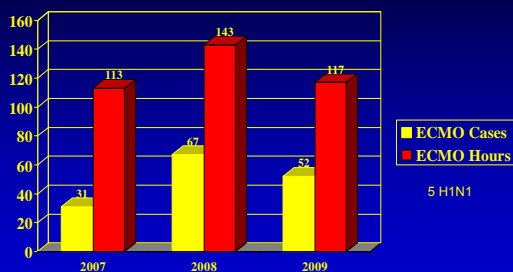
- Personnel
- Supplies
- Equipment
- Quality Management



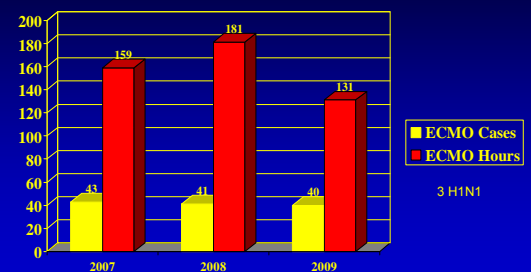
Hanuola ECMO 2010 and Beyond

- Local and National ECMO experience
- Kapi'olani agreement
- Stae of Hawaii H1N1 strategic plan
 - Perfusionists
 - ECMO Specialists
 - Education
- BioTronics arrangements

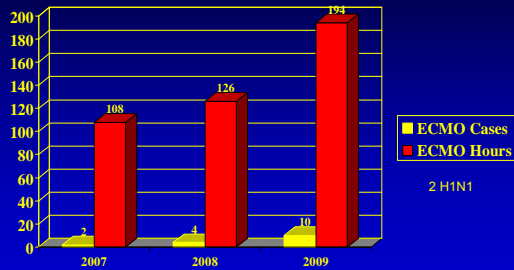
UPMC Presbyterian ECMO Experience



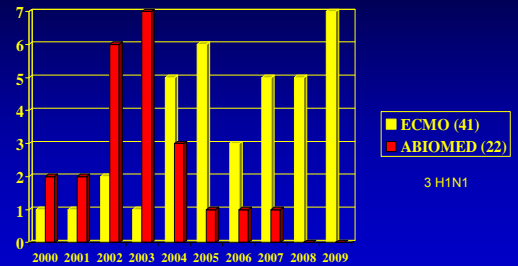
UPMC Children's ECMO Experience



Kapi'olani ECMO Experience



UPMC Transport Experience



UPMC BioTronics Agreement

- Leadership
- Quality assurance
- Monitoring
- On-call coverage
- Transport services
- Training
- Consultation



Hawaii Personnel

Primary Perfusionists

Kristen Costales, CCP
Eugene Garrett, CCP
Pete May, CCP
Mark Yanogacio, CCP
Shilpa Nair, CCP
Brian Costales, CCP

Relief Perfusionists

Thomas Hogan, CCP
Lisa Hogan, CCP
Kent Kelly, CCP
Don Koch, CCP
Don Maloney, CCP
Elizabeth O'Malley, CP

Relief Perfusionists

Thomas Hogan, CCP
Lisa Hogan, CCP
Kent Kelly, CCP
Don Koch, CCP
Don Maloney, CCP
Elizabeth O'Malley, CP

Local Perfusion Activity

- Kapi'olani Medical Center for Women and Children
- Queens Medical Center
- Kuakini Medical Center
- Kaiser Medical Center
- Staub Hospital
- Hawaii Medical Center
- Tripler Army Medical Center



Relationships

- Quality
- Service
- Fiscal responsibility





www.biotronics.com

BioTronics, Inc.
1370 Beulah Road
Pittsburgh, Pennsylvania
888-881-5218



CALENDAR OF EVENTS

September 10-12, 2010 – Team SUNY 2010, SUNY Upstate Medical University, Syracuse, NY. For more information and online registration, please visit www.ec.upstate.edu/chp/cp/TeamSUNY/home.html

September 18-19, 2010 – North Carolina Society of Perfusionists Fall Meeting, Hilton Garden Inn at Southpoint, Durham, NC. For more information, visit <http://ncperfusion.org>

October 1, 2010 – Call for Abstracts opens for the 49th International Conference, April 13-16, 2011, New Orleans, LA. Visit www.amsect.org for more info.

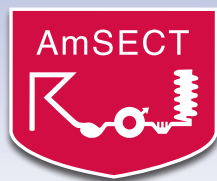
October 6 - 9, 2010 – AmSECT's Perfusion Safety & Best Practices in Perfusion, Fairmont Royal York Hotel, Toronto, Ontario. For more information, visit www.amsect.org/sections/education/Best_Practices/

October 22-24, 2010 – Autologous Blood Therapy Course, Jameson Inn Pearl, MS. For more information, contact Glenda Courtney (601) 824-3915, PRFUZN@Bellsouth.net <http://autologous-bloodtherapycourse>

October 29-30, 2010 – 27th Annual Scientific Meeting/Australian and New Zealand College of Perfusionists, Seaworld Resort, Gold Coast, Australia.

November 30, 2010 – Willingness to Serve applications due. Please visit <http://amsect.societyhq.com/members/wtsa.iphtml> to submit.

November 30, 2010 - National Award Nominations due. Visit the Members Only section at www.amsect.org.



AmSECT

Today

September/October 2010 • Volume 13 Issue 5

MESSAGE FROM THE PRESIDENT

Safety and Evidence-Based Practices

By Susan J. Englert RN CNOR PBMT CCP
AmSECT President

It almost goes without saying that experience and knowledge, translation in using judgment skills, and being watchful during a case are critical components for the safe delivery of extracorporeal support. Cardiopulmonary bypass, blood management, heart failure therapy and support, ECMO, and associated perfusion-directed services are lifesaving, but they also carry the potential to seriously injure or kill a patient.

The estimated risk of death or a serious injury during cardiopulmonary bypass is one in 2,500 procedures. This is 100 times greater than the risk from anesthesia. A plethora of statistical data abounds with ratios of serious injuries or deaths to cases pumped, or for certain CPB procedures done. Many states collect and publish for public consumption the CABG and mortality ratios for surgeons and hospitals. To the best of my knowledge, the specific hand of a perfusionist in contributing to these adverse medical outcomes is not recorded. It can only be guessed.

There already has been, and will continue to be, the adoption by private insurance compa-

nies, the federal Medicare program, and states the use of evidence-based medical practices and patient outcomes for the identification of medical

care delivery process problems. These are clinical practice factors that can be shown to contribute to the manifestations of less than optimal patient care outcomes. These activities are occurring in hospital systems, within surgical departments, and within programs, with the intent to identify and evaluate clinical practice risks and take steps to improve quality assurance. Some of this information also gets translated into uses such as identifying problem hospitals or linking, for example, Medicare hospital payment rates to a hospital's achievement of benchmark standards of care for patients as delivered by the care providers. In the case of perfusion, to the surgical team members and



Susan J. Englert RN CNOR
PBMT CCP

Continued on page 15

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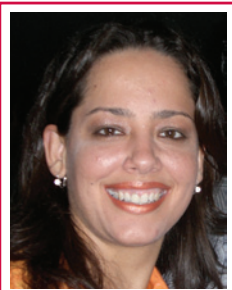


SEPTEMBER / OCTOBER THEME ARTICLE

Safety / Best Practices

By **Nadia C. Azuero, BS CCP LP**

Atlanta, GA



Nadia C. Azuero BS CCP LP

Safety is defined as the condition of being safe: freedom from danger, risk, or injury. It also extends to technology stating, a device designed to prevent accidents, as a lock on a firearm preventing accidental firing. Perfusionists would think the second definition applies more to our profession, but personally, I believe the first one is more crucial. The second definition is the preventative measure to the first one. In our profession, we have progressed in taking safety measures behind the pump to protect the patient and ourselves. Utilizing equipment like level detectors, air bubble detectors, high-pressure alarms for cardioplegia and the arterial pump, all linked to servo-regulation to the arterial pump as a safety measure to avoid pumping air or runaway pump. These methods have become standard in the industry but still the most important safety measure is the attentiveness of the perfusionist.

To parallel, the airline industry received the approval of Congress to overhaul the safety rules for pilots. This all came about after the commuter airline crash February 12, 2009 in western New York. The cause of this crash? Fatigue, something that we can all relate to, something that plagues every healthcare professional. However, this issue was addressed in 2003 and 2004 when it was reported that many residents made mistakes from excessive fatigue of 36-hour call shifts. That time has since been reduced to 30-hour shifts every other day. And while perfusion does not require such a rigorous call schedule, we have our own set of fatigue issues. I cannot speak for most of the community since every program operates differently. However, we can all assume that being understaffed for the duties required by the institution, such as ECMO and VADs, modalities that require around the clock monitoring, will deplete the staffing requirements when scheduled cases must continue. The attentiveness is definitely diminished. Another example is smaller programs of 450 cases or fewer being staffed with the bare minimum. When caseloads and emergencies get hectic, fatigue increases. Perhaps, salary requirements can be partially blamed. Since the base salaries have had to go up in recent years, that leaves fewer funds available to hire additional full time employees. The root of the issue is as personal as a program's protocols and is left for each individual Chief to decipher. However, it is a topic to be considered to meet the safety requirements of being alert during the needed hours for work.

As professionals, I would like to think that we all do our part to protect each other in times of strenuous work and long hours. However, fatigue is still an issue that needs to have an eye kept on it. Sleep deprivation, being the main culprit of fatigue, can cause drastic mistakes behind the pump that our first line of defense, safety systems, may not be linked to. Such examples can be accidentally shutting off the pump during bypass, infusing the wrong medications, over diluting, or even hypoperfusing. Knowing the signs of fatigue and allowing ourselves, as professionals, sufficient breaks, rest and recovery, can avoid all the issues mentioned above. If we can all avoid becoming a statistic, we have served our profession right. Working together as a team can help prevent many of these issues.

References:

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<http://www.thefreedictionary.com/safety>
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http://www.nifc.gov/wfstar/reports/signs_of_fatigue.pdf

Membership Questions?



Contact Kim Battle
kim@amsect.org



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COMMITTEE SPOTLIGHT: ICEBP

Each 2010 issue of AmSECT Today will highlight one of the many AmSECT committees. For this issue, the spotlight is on the International Consortium for Evidence-Based Perfusion (ICEBP).



International Consortium for Evidence-Based Perfusion (ICEBP)

It's been 11 years since the landmark report published by the Institute of Medicine (IOM) entitled "Too Err is Human." This report was the first of its kind to study the impact of inpatient hospital medical errors. The IOM concluded that nearly 98,000 patients die annually from potentially preventable medical errors, and strongly suggested that it should be classified as a national epidemic. In 2004, the HealthGrades Patient Safety in American Hospitals study calculated that the previous IOM study underestimated the incidence of patient death from medical error by 50%. Consider this: if the above-mentioned calculations are accurate, then approximately 2 million people have mistakenly died in this country at the hands of healthcare professionals since the publication of the IOM report.

Since the landmark IOM report, there has been a growing interest among many in the healthcare field in studying how other industries have tackled issues of safety and quality. For interest, there have been several comparisons drawn between healthcare and the airline industry. Many hospitals and health organizations point to the incredibly low incidence of airline tragedy, due in large part to the strict policies and procedures adopted by this industry. While many in healthcare have developed and implemented policy and procedures manuals as a way of preventing unintended errors, our industry performs poorly as compared to the airline industry. For instance, the number of estimated annual preventable patient deaths is equivalent to 390 jumbo jets full of passengers dying every year. One can't begin to imagine the negative impact on the airline industry if at least one jet is fatally crashing every day.

As perfusionists, we need to ask ourselves what we can do to improve the cardiac surgical culture of safety. We need to be receptive to breaking the mold, and carefully examining solutions for safety at the local, national and international levels. The International Consortium for Evidence-Based Perfusion (ICEBP), a committee within the American Society of ExtraCorporeal Technology, has focused their

efforts on the identification and diffusion of safe practices during cardio-pulmonary bypass.

The ICEBP

Mission: The International Consortium for Evidence-Based Perfusion (ICEBP, <http://www.bestpracticeperfusion.org>) is a partnership and collaboration between perfusion societies, medical societies, clinicians and industry to improve continuously the delivery of care and outcomes for our patients.

Vision: To achieve this mission, we will focus our energies in two principle areas:

Guidelines

- Review, comment, and/or endorse evidence-based guidelines concerning the practice of cardiopulmonary bypass
- Collaborate with medical societies in the development of guidelines concerning the practice of cardiopulmonary bypass Registry
- Create an international perfusion registry and facilitate its implementation
- Identify gaps between current and evidence-based clinical practice

In order to succeed, the ICEBP will foster communication amongst its membership through a web portal, scientific conference, and internal and external publications.

Guideline Writing

The mission of the Guideline Writing subcommittee is to develop evidence-based clinical practice guidelines for cardiovascular perfusion. This committee has adopted the methodology used by the American College of Cardiology/American Heart Association (www.acc.org/qualityandscience/clinical/manual/manual_index.htm) Guideline Writing Group.

One of the obstacles discovered early was being able to manage the large volume of work and large number of workers needed to actually achieve our goals of developing guidelines fashioned on the strict ACC/AHA methodology. We needed to actually develop some tools to aid us in each facet of the work. The Flinders Medi-

cal Centre group in Australia has developed an online tool, "Guideliner" to help in this endeavor.

Simply put, "Guideliner" helps us organize the review of the abstracts and structures our paper reviews, electronically filing all of the responses enabling the final synthesis of the vast literature to be organized and structured. We are now starting to see some output from groups using "Guideliner" and this promises to be pivotal to the generation of reproducible and consistent work in the future.

Currently, three projects are being undertaken.

- Development of Perfusion Guidelines in conjunction with the Society of Thoracic Surgeons and Society of Cardiovascular Anesthesiologists. Currently these guidelines are in their formative stage, although some sections are more developed than others.
- Update of the Ferraris Perioperative Blood Management Guidelines in conjunction with the Society of Thoracic Surgeons. This work is nearing completion, with a draft manuscript currently under review by co-authors.
- Development of the perfusion guidelines by the ICEBP, especially related to the inflammatory response. These guidelines are progressing well, with the hope of completion of all sections and a manuscript by the end of 2010.

A progress report on all these guidelines was presented at Amsect's 48th International Conference in Reno, Nevada.

Future Work: Requests for Volunteers

Although lots of work is already done, it is never complete. Therefore, the Guidelines Writing Subcommittee is seeking volunteers to help in subsequent projects. The ICEBP will provide support and resources, and you don't need to be a Guideline Specialist to enroll in this interesting endeavor. All are welcome to contribute, including students, and practicing perfusionists. Volunteering could include both short and long-term commitments.

If you're interested, please contact Rob

COMMITTEE SPOTLIGHT: ICEBP

Baker or David Fitzgerald for further assistance.

Publications from the Guideline Writing Committee

The Guideline Writing Subcommittee has recently published two pieces of work:

- An editorial on Perfusion Data in Scientific Journals: Perfusion Standards of Reporting Trials (PERFSORT) just published in *JECT (J Extra Corpor Technol.* 2010 Jun;42(2):101-2.)
- "Effect of the Perioperative Blood Transfusion and Blood Conservation in Cardiac Surgery Clinical Practice Guidelines of the Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists upon Clinical Practices" currently published in both *JECT (J Extra Corpor Technol.* 2010 Jun;42(2):114-21) and *Anesthesia & Analgesia (Anesth Analg.* 2010 Aug;111(2):316-23. *Epub* 2010 May 20). Pediatric Committee
- The Pediatric Committee has continued to develop and support its collaborative relationship with the STS Congenital Database Taskforce, Multi-Societal Database Committee for Pediatric and Congenital Heart Disease (MSDCPHD), and the AmSECT Pediatric Committee. In 2009, the ICEBP Pediatric Subcommittee, in collaboration with the AmSECT Pediatric Committee, developed new variables and definitions for the 2010 Update (version 3.0) of the STS Congenital Database that focus on the practice of congenital and pediatric perfusion. A manuscript describing the process and resulting variables and definitions that were accepted by the STS Congenital Database Taskforce has just been published in the *World Journal for Pediatric and Congenital Heart Surgery (WJPCHS)*. (*World Journal for Pediatric and Congenital Heart Surgery* April 2010 1: 34-43)
- We have worked with the editor of this journal to offer free online-access to this article. Anyone can register for free online access to Volumes 1-3 of WJPCHS at the following URL: www.sagepub.com/journalsProdDesc.nav?prodId=Journal201975. Through the strength of the STS Congenital Database (over 90 participating congenital heart surgery centers) we hope to identify associations between congenital perfusion practice and patient outcome.

Registry Subcommittee

In the Mission and Vision statement of the ICEBP, it is mentioned that, '...to achieve the mission, an International Perfusion Registry should be created and its implementation facilitated.'

The ICEBP has designed and developed

the ICEBP International Perfusion Registry structure for collecting and analyzing data related to cardiopulmonary bypass. This registry would fill gaps in our knowledge that is not currently covered by other registries in cardiac surgery. It would serve a need to provide feedback to clinicians on the best practices in perfusion.

The first iteration of this registry focuses on the following areas:

- Patient demographics (to adjust for potential patient-level confounders)
- Compliance with published perfusion guidelines
- Cell processing and filtration
- Renal Management
- Factors that influence low Ejection Fraction among patients with normal ejection fraction

The regional cardiac surgery quality collaborative in the state of Michigan has agreed to serve as a pilot organization for this registry. The MSTCVS Quality Collaborative (www.mstcvs.org/qc) promotes and shares optimal processes of care and cardiac surgery outcomes and implements quality improvement initiatives based on regional and national data as well as clinical research and evidence based cardiac surgery practice and guidelines.

To emphasize the approach of the pilot phase (currently underway), the Executive Committee has drafted a White Paper describing the ICEBP International Perfusion Registry. It focuses on the concept, purpose, practical workout, functionality and goals of this initiative.

You can download the International Perfusion Registry White Paper on the Registry Subcommittee page (www.bestpracticeperfusion.org/sections/committees/Registry/index.html).

Perfusion Safety & Best Practices Meeting 2010

AmSECT's Perfusion Safety & Best Practices in Perfusion 2010 marks our second venture outside of the USA, allowing us to explore the unique position of the ICEBP as a group with international expertise and participation. This year we are building on the theme initiated in New Orleans in 2009 with the union of Perfusion Safety and Best Practices through hands-on simulation training and the knowledge translation.

Date: October 6-9, 2010

Location: The venue will be Toronto, Ontario, Canada with the first two days of the conference hosted at the CAE/ Michener Centre for Advancement of Simulation Education (CASE), a unique private/public partnership between the CAE Healthcare (www.cae.com/en/healthcare/home.asp) and Michener Institute of Applied Health Sciences (www.michener.ca/). Such a venture leverages over 60 years of best practices acquired in the aviation simulation industry with 50 years of dedicated experience in health care education. With 20,000 square feet of simulation studios, including 24 fully-functional Objective Structured Clinical Examination (OSCE) suites, the centre features flexible studio space that can be used by a variety of healthcare teams including students and practicing professionals in the disciplines of medicine, nursing, imaging, radiation, cardiovascular perfusion and many more.

Keynote Speaker: To complement our program, we are extremely fortunate to have as our keynote speaker Dr. Amitai Ziv MD MHA. Dr Ziv is a world-renowned expert in the field of medical simulation and has been invited to give keynote talks at multiple medical conferences worldwide, as well as Grand Rounds at leading medical institutions around the world. Dr. Ziv is the Deputy Director of the Sheba Medical Center at Tel Hashomer, Israel, and is responsible for Risk Management, Quality Assurance and Medical Education. He is also founder and Director of MSR - the Israel Center for Medical Simulation. He is also the recipient of national and international awards including The 2007 Charles Bronfman Award for Humanitarian Action and The 2007 Michener Honorary Diploma of Health Science Award for leadership and commitment to the Michener Institute of Applied Health Sciences.

Rich Agenda: We are extremely proud to provide our delegates the unique opportunity to experience a dedicated high fidelity simulation environment with four concurrent simulation sessions. This opportunity, coupled with our 10 didactic sessions (focused on the perfusion safety, use of simulation, ICEBP registry and guideline development and implementation), makes this an extraordinary meeting to be savored and not missed.

Online Newsletter regarding the ICEBP

By going to the followings link, you can subscribe to the ICEBP newsletter!

www.bestpracticeperfusion.org/sections/Newsletter/index.html

We would like to thank Medtronic Inc. for their contribution of translating our latest newsletter into Spanish.

To Register, please visit:
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Citations:

- 1 Shann et al, An evidence-based review of the practice of cardiopulmonary bypass in adults: A focus on neurologic injury, glycemic control, hemodilution, and the inflammatory response; *Journal of Thoracic and Cardiovascular Surgery*; 2006;132:283-290.
- 2 Ferraris et al, Perioperative Blood Transfusion and Blood Conservation in Cardiac Surgery: The Society of Thoracic Surgeons and The Society of Cardiovascular Anesthesiologists Clinical Practice Guideline; *Annals Thoracic Surgery*; 2007;83:S27-86.
- 3 Preston et al, Clinical Gaseous Microemboli Assessment of an Oxygenator with Integral Arterial Filter in the Pediatric Population; *Journal of ExtraCororeal Technology*; 2009; 41:226-230.

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FEATURE ARTICLE

Say "Hello" To ECMOjo

By Gary Grist RN CCP

Children's Mercy Hospital and Clinics
Kansas City, Missouri



Gary Grist RN CCP

Perfusion simulators for training are becoming very popular and a new Source Forge open source simulator from Hawaii is now available to anyone wishing to test their skills in using a heart/lung machine to keep a patient alive: <http://ecmojo.sourceforge.net>. The latest version of "ECMOjo" became available in February 2010. ECMOjo is not a typographical error; it is a contraction of two words, ECMO and mojo (a magical charm). The program was developed by the Telehealth Research Institute at the John A. Burns School of Medicine of the University of Hawaii, under a grant from the Department of Defense. The Hanuola Center uses this and other tools to train its physicians, nurses and other personnel in the basics of ECMO. The Hanuola Center is the ECMO Program of Hawaii, which serves to provide pediatric extracorporeal life support services for Hawaii and the Pacific Rim region. The simulator was developed in cooperation with Tripler Army Medical Center, Kapi'olani Medical Center for Women and Children, Kaiser Permanente of Hawaii, the University of Hawaii and the University of Pittsburgh Medical Center. The project manager is Mark T. Ogino, MD, Hanuola ECMO Medical Director. Among many other contributors are two perfusionists who participated in the simulator's development, Kristen Costales CCP, ECMO Perfusion Coordinator and Kent Kelly CCP.

ECMOjo is an open source program, which means it is free to use online or for download under the terms of the Berkeley Software Distribution License. It is available for Windows, Macintosh, Linux and UNIX operating systems. The simulator uses a graphical interface, delightfully illustrated by artist Kaleiohu Lee.

The ECMOjo screen is divided into left and right sides. On the left, the graphic interface shows a patient (an infant) attached by blood tubing to a heart/lung (ECMO) pump on the right side.

On the left side, the patient's blood pressure, arterial blood saturation, heart rate, venous blood saturation, temperature, respiratory rate and other parameters are displayed above the patient. Modifications to the circuit cause changes to the patient values. For example, if the VA ECMO pump flow is increased, the patient's blood pressure goes up. If the sweep gas flow is reduced, the patient's pCO₂ increases. If the water temperature is reduced, the patient's temperature goes down. If the pump stops altogether, the patient will rapidly decompensate in all vital areas. Lab values such as arterial blood gases, hematology (CBC & coags), electrolytes, lactate, and ACT values can be reviewed and new values obtained. These can also change with pump changes; for example, increasing acidosis and lactate values correlating to decreasing pump flow. Chest X-rays and head ultrasound images can be viewed and cardiac ECHO reports read. Ventilator parameters can be changed from rest settings to emergency settings. Another indicator shows if the patient is on venoarterial or venovenous ECMO.

Placing the cursor over the patient brings up a menu that allows the operator to suction the endotracheal tube, check the cannulae for bleeding or kinks, assess urine output, assess level of sedation and even check for a dirty diaper. A short summary of the patient's diagnosis and current status can also be viewed. During the simulations, the patient status may worsen. This is visually enhanced as the patient becomes progressively paler and

bluer. This visual change provides added urgency to each simulation.

On the right side of the screen is the ECMO circuit with its disposable components and hardware. The circuit can be checked or changed with the touch of a button. The pump flow can be regulated. The sweep gas FiO₂ and flow can be controlled. The heater temperature can be changed or the unit replaced. The circuit pressure monitor alarm limits can be adjusted. There is a bubble detector and four interventional sites that allow the operator to administer PRBC, FFP, platelets, heparin, catecholamines, 5% albumin or sedatives.

On the top right is a timer/clock used during simulations to assess the operator's speed at solving the various problems presented in the simulations. A red light flashes and an audible alarm sounds when the infant's vital signs become abnormal. The audible alarm is unique and almost comical. It is reminiscent of the klaxon horns used in submarines ("Dive! Dive! Dive!"). Anyone in the room when the game is being played is inevitably drawn to see the cause of the strange noise.

On opening the program, the operator can choose tutorials (Overview, Introduction, Detailed and Advanced) to train in its use. The operator can also choose to use venoarterial or venovenous cannulation, a silicone or hollow fiber oxygenator, and a roller or centrifugal pump. After gaining familiarity with the fundamentals, the operator can choose from two broad categories: Scenarios and Simulations.

Scenarios are step-by-step training exercises that teach the operator about the various procedures needed to deal with circuit and/or patient problems. These include such things as routine circuit checks, coming off pump and going on pump, pump failure, air in the arterial line, circuit failure, temperature control, sweep gas control, oxygenator rupture, high system pressures, etc.

Simulations are exercises to test the operator's skill in recognizing a problem and correcting it. During the simulations a timer counts down to warn that some problem will soon develop. Once the counter reaches 'zero', another timer starts to measure the time needed for the operator to diagnose the problem and select the appropriate solution. For example, increasing system pressures might stop the pump, causing the infant's blood pressure and heart rate to fall as well as arterial desaturation. The cause might be a kinked arterial cannula, which is corrected very simply. On the other hand, the high system pressure might be caused by a developing DIC which is clotting the oxygenator and which can only be detected by a review of the hematology labs and only corrected by changing out the entire circuit. If the cause of the infant's deterioration cannot be readily determined, immediate resuscitation steps may be needed, such as infusing volume, giving catecholamines, or going to emergency ventilator settings. These may buy time until a solution can be found and the pump restarted. Other simulations might deal with equipment failure, progressive acidosis, platelet consumption, agitation, a large blood loss from an accidental arterial decannulation, or a number of other things. If the problem is diagnosed and solved before the allotted time expires, the patient survives. Otherwise, the patient expires and the operator fails the exercise.

ECMOjo is still a work in progress. There seem to be a few bugs in the system. But, the website has contact links to the Telehealth Research Institute and encourages feedback by users to help in solving these problems.

On first impression, ECMOjo seems like a quaint, fun, ECMO video game, but it is really much more sophisticated than it first appears. Even an operator with 40 years of perfusion experience and 25 years of ECMO experience (like me) can find this program quite challenging. So, say hello to ECMOjo and have some fun! You might even learn something along the way.

GOVERNEMENT RELATIONS COMMITTEE

Federal Changes in the Delivery of Health Care

By Lee Bechtel

Director, Government Relations Committee

Robert D. Longenecker BS LCP CCP

Chairman, Government Relations Committee

There may be a few people in the country that don't know about the recent enactment of the comprehensive health care system reform law, otherwise known as the Patient Protection and Affordable Care Act (PPACA) of 2010. This new law, to be implemented over the next few years, includes several future Medicare hospital and cardiovascular physician payment policy changes, along with the imposition of new medical device tax on manufacturers of cardiovascular equipment and supplies used by perfusionists in the operating room.

AmSECT's Government Relations Committee is focused on perfusionist state credentialing for protection of clinical practice entry requirements to better ensure patient safety and the competent delivery of perfusion services. However, knowledge about other public policy changes that indirectly impact the profession is also valuable. Examples are the safety and effectiveness of medical devices used by perfusionists and regulated by the Food and Drug Administration (FDA), changes in Medicare CMS (Center for Medicare and Medicaid Services) coverage, and reimbursement policies impacting hospitals and physicians for providing high cost surgical procedures.

The members of the Government Relations Committee share the opinion that knowledge regarding such matters should not be excluded from a perfusionist's day-to-day clinical practice. Perfusionists grow wise in the science, techniques, and technologies in their own profession, but they need to have some fundamental understanding regarding the external governmental influences and factors impacting their work environments. These regulatory issues are important whether perfusionists are employed by hospitals, surgeon groups, or independent contract providers of services. With this in mind, the following overview highlights some of the coming changes in Medicare payment policy. Other health care reform changes will be discussed in *AmSECT Today* with future concise GRC articles.

Medicare Bundling of Physician and Hospital CABG and Heart Valve Replacement Case Payment

In the 1990's the Medicare Participating Heart Bypass demonstration project found that bundling of hospital Diagnosis Related Group (DRG) payments and Medicare Physician Fee Schedule (PPS-Prospective Payment System for physicians) payments could reduce Medicare costs for these types of high cost cardiovascular procedures. In 2008, the Medicare Physician Advisory Committee (MEDPAC) recommended to the Congress, and the Congress approved, a two-year pilot program for these types of cases. Five hospitals were selected from different parts of the country to participate.

At these pilot project hospitals, each hospital would receive a combined payment amount that included the DRG payment amount and the



Lee Bechtel



Robert D. Longenecker
BS LCP CCP

cardiovascular surgeon PPS payment amount. To get Medicare beneficiaries to use these hospitals, they would receive an incentive payment that could be used as they saw fit. The pilot project Medicare cost data collected showed a combined 5% cost savings reduction for CABG and heart valve cases done in these five hospitals.

In the Medicare sections of the Patient Protection and Affordable Care Act (PPACA) (PL 111-148), the CMS has been given the regulatory authority to expand the pilot program to a two-year Regional Demonstration program starting in 2011, and authority to convert this to a national payment system in 2013 or thereafter, based on the collection of more cost and utilization data.

Two adjustments when converting to a national payment system would also come into play. First, university and teaching hospitals would be exempt from the global fee payment for hospital and physician services. Second, rural-based hospital global fee reimbursement amounts would be adjusted to reflect a surgical case index number. Under current Medicare hospital DRG payments, rural-based hospitals already receive a percentage increase from what is paid to urban hospitals to reflect the higher cost of hospital care, due to unique manpower and demographic issues in less populated areas.

“The future ain't what it used to be.”

- Yogi Berra, Baseball Hall of Fame Player and Former New York Yankees Coach

Physician/Cardiovascular Surgeon Reaction

In the June 2008 report and recommendation to Congress on bundling of high cost surgical procedures, not just CABG and heart valve cases, the MEDPAC argued that even though hospital DRG payments were already a bundled payment. They felt that extending the concept to physicians would encourage doctors and hospitals to

work together to control Medicare program costs and improve patient quality of care. Of course, cardiovascular physicians and other medical specialty physicians took issue with the concept of giving hospitals too much control over physician payment rates. Sending a lump sum payment might potentially provide an incentive to skimp on medical care services to maximize hospital profits.

While these arguments were generally rejected during the Congressional and public debate over the Medicare reimbursement reforms promulgated and subsequently enacted into law, a post-passage financial analysis was performed by the CMS covering the complete range of Medicare payment system reforms. It showed that hospitals and hospital administrators will be facing tough challenges as well. Without delving into the other major payment policy changes directly impacting the financial viability of hospitals in the future, the CMS has estimated that one in six hospitals in the country (15%) could very well go bankrupt over the next ten years. For example, the hospital DRG payment rate for 2011, as now scheduled, will be further reduced by 2.9%. This reduction will be included in the bundled payment rate for the global fee paid to hospitals for high cost surgical procedures.

Indirect Impact on Perfusion Practice and Future Income Potential

Reimbursement changes by the Federal Government are not the only change we will see. There is a newly enacted medical device tax on manufacturers of cardiovascular equipment and supplies used by perfusionists and all other health care professionals. The Health Information Technology for Economic and Clinical Health (HITECH) enacted in 2009 mandates hospitals to have a seamless interoperable patient medical record information system by 2014 or face Medicare payment penalties. It remains to be seen how these new laws will affect perfusionists, regardless of how they are employed or conduct their clinical practices. The impact on salaries, benefits, and the ability to continue to provide innovation in the delivery of patient care are largely unknown. This is not only true of the perfusionist community, but also every other health care professional.

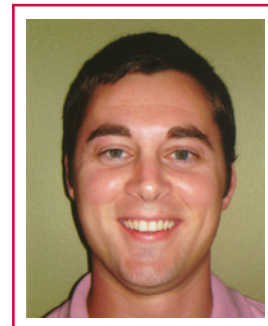
These changes upon us clearly demonstrate what a famous New York Yankees coach said many years ago – “The future ain’t what it used to be”. The health care industry in the United States is likely to be one of constant change for the foreseeable future.

THEME ARTICLE

“Blue to Red, Don’t Run Dry, and Don’t Gel”

By William Mathew Medlin RRT RCP BS CCP
Savannah, GA

As a graduate of the Medical University of South Carolina, I heard the faculty members always instilling very important safety information toward our careers as skilled perfusionists. The mnemonic above is one I will never forget because it displays imperative safety information to our practice in the operating room. I always compare operating the heart-lung machine to flying an airplane and how we hold the patient’s life in our hands at all times. We should always strive to be quick on our feet, ready to troubleshoot at any time.



Mat Medlin RRT BS CCP LP

A perfusionist should always perform a pre-bypass checklist and record the results. These checklists can become routine and items are often overlooked, so it is critical to perform the checklist slowly and thoroughly so no errors occur. Once cardiopulmonary bypass is initiated, there are a few safety checks to consider:

On Bypass Safety Checks

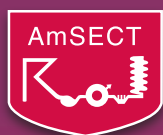
- ✓ Blood flow at proper rate
- ✓ Arterial line pressure is normal
- ✓ Oxygen started at proper flow/concentration
- ✓ Oxygen saturations normal
- ✓ Patient’s MAP normal
- ✓ Temperature appropriate
- ✓ Coagulation status acceptable
- ✓ Vaporizer turned on at appropriate level

Safety Devices Checked

- ✓ Bubble Detector ON
- ✓ Level Detector ON
- ✓ Manifolds in right position
- ✓ Drugs given as required
- ✓ Oxygen analyzer ON

The best safety device available today is the perfusionist, one who is well trained, experienced, and qualified to handle routine as well as emergency situations. It is doubtful that anyone would encourage an in-depth conversation with the pilot of an airplane during final approach and landing. Distracting the perfusionist with additional responsibilities and gadgets can, and has, created the same terrible results.

Always remember that patient safety is our number one priority! Perfusionists should always train themselves to ‘do it the same way’ every time; this way, in emergent procedures you cover all your bases. I really have a great appreciation for perfusion education, because one of the main objectives is toward perfusion safety. Now, with simulators in use, errors can virtually be eliminated.



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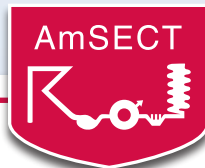
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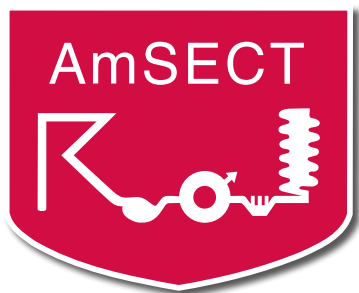


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Wednesday, October 6 - High Fidelity Hands-on Simulation Sessions at CAE-Michener Simulation Centre

These one-on-one sessions offer the perfusionist the opportunity to participate in a structured hands-on, interactive simulation of cardiopulmonary bypass. The appointments will be assigned on a first-come, first served basis, and space is limited to 28 participants. There are four opportunities for hands-on sessions listed below, and each session lasts two hours (30 minutes prebrief, 50 minutes simulation, 30 minutes debrief). Please indicate your 1st, 2nd and 3rd choices for Simulation Hands-on Workshops. Your appointment will be included in the email confirming your registration and confirmation will be granted with the presentation of the ticket you will find in your registration packet. *It is highly recommended that you confirm your session assignment prior to making your travel arrangements.* If you are unable to keep your appointment, please contact AmSECT as soon as possible so the session can be reassigned.

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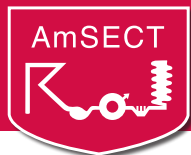
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PRESIDENT'S MESSAGE

Continued from page 1

surgeons. Evidence-based medical practice guidelines are here now, and will be even more prominent in the structure of our future health care system.

As perfusionists know, the most common contributing factors to patient safety in the performance of a CPB case are equipment malfunctions or operator error. Operator error may not just involve a single perfusionist. It can include problems that come from miscommunications between surgical team members and/or the surgeon. More often than not, despite due diligence in the conduct of a pre-bypass checklist, running calculations, and selecting equipment, every patient is their own island of yet-to-be manifested associated medical conditional influences. In other words, expected responses do not turn out as anticipated and have to be managed in order to maintain a patient within the accepted normal ranges for a number of on-pump measurements - venous drainage, blood gases, cannula disruption, occlusion of cardioplegia lines, you name it.

Attention to safety and the use of critical judgment skills in response to a patient's needs, in support of the patient's on-pump condition during a CPB case, in support of the surgeon and surgical team, to successfully get to the endpoint of having a good patient post surgical case medical outcome is the goal. Added to these influences and factors, are new challenges that arise with the incorporation of new techniques and/or devices.

In the bigger picture of delivery of quality in performing perfusion services, these safety factors and the associated patient outcomes also contribute to the use of evidence-based perfusion, or best practices. In developing the scientific sessions for its perfusion best practices symposiums, AmSECT has actively engaged the International Consortium for Evidence-Based Perfusion (ICEBP).

Safety and the performance of best practices go hand in hand with continued competency assessment, which is critical for reducing medical errors, either equipment or operator related. The beginning use of CPB simulation in a few perfusion training programs poses a tremendous advancement for the whole of the profession. Its use, in my view, has clinical practice value to currently practicing perfusionists, and not just to students. Articles about this topic appeared in the March/April and July/August editions of AmSECT Today. Clinical simulations have been used in other professional medical fields for many years. Its application to the performance of perfusion, and the techniques of this not-so-new technology, will be on display at AmSECT's upcoming Perfusion Safety/Best Practices 2010 symposium on October 6-9, in Toronto, Ontario.

Having been a practicing perfusionist for 28 years, I am envious of the recent use of cardiovascular simulation. It was not around when I trained, which is probably why we older perfusionists have more worry wrinkles and gray hair. Nothing does better than real world experience and the knowledge translation that takes place during a case. This works well when things go right, but not so well when it comes to making split-second decisions to prevent serious harm to a patient. With simulation, the learning curve for students is reduced, and potential safety issues avoided as they start pumping their own cases. Consideration should be given, eventually, for voluntary simulation for perfusionists already in practice. In either case, simulation mixed with real world cases of things gone wrong, could lead to the improved delivery of perfusion services, and potentially improved CV patient medical outcomes.

Not all individual patient safety circumstances can be pre-planned and managed in advance of a case. However, attention to and effectively dealing with safety issues does contribute to the execution of perfusion best practices. The evidenced-based use of standards and guidelines in the performance of perfusion can serve individual perfusionist needs, and positively contribute to the conduct of our profession now and in the future.

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STUDENT ViewPoint

Safety During Cardiopulmonary Bypass

By Kayla McClintock
Rush University

How do we maintain safety during cardiopulmonary bypass? Since cardiopulmonary bypass was first used in the early 1950s, there have been great attempts to ensure the patient's safety. Due to advancements in technology, the practice of perfusion and cardiopulmonary bypass have become exponentially safer. Circuits have become simpler and more safety devices have been incorporated as well. However, it is not only the pump that has improved; the profession of perfusion has also come a long way.

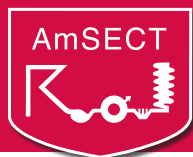
Perfusion first began as on-the-job training and has progressed all the way to national accreditation. Educational programs have also advanced to offering a Master's Degree in Perfusion Technology. With the new developments of increasing technology, it is just as important for the perfusionist to stay up-to-date as well. I feel that the expertise of the perfusionist is the most important key to cardiopulmonary bypass safety.

The heart-lung machine and the perfusionist are not the only factors in contributing to patient safety. Conduct and communication in the operating room as well as surgical technique, are also major players. It is extremely important to maintain a professional attitude in the OR and to be able to communicate promptly and effectively. Listening and being on your toes at all times can greatly contribute to patient safety from what I have seen. With technological advancements concerning the pump, there are also advances being made in surgical technique, such as the increasing popularity of minimally invasive procedures. Ultimately, these new techniques will also lead to greater patient safety.

The level detector, the bubble detector, autoclamps, pressure, temperature and gas monitors are all safety devices that I have encountered so far during my clinical rotations. They all greatly contribute to cardiopulmonary bypass safety by eliminating danger to the patient. However, it takes more than technology and safety devices to perfect the practice of perfusion. It also requires a well-educated professional to achieve maximal safety and cardiopulmonary bypass success.



Kayla McClintock



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|---------|--|---|
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| 2. D | 8. True | 12. False - While damage occurs at temperatures about 42°C, no damage has been reported for temperatures below 4°C. |
| 3. C | 9. C | 13. A |
| 4. True | 10. False - The supine position with right hip elevated, known as the left lateral position. | |
| 5. B | | |
| 6. C | | |



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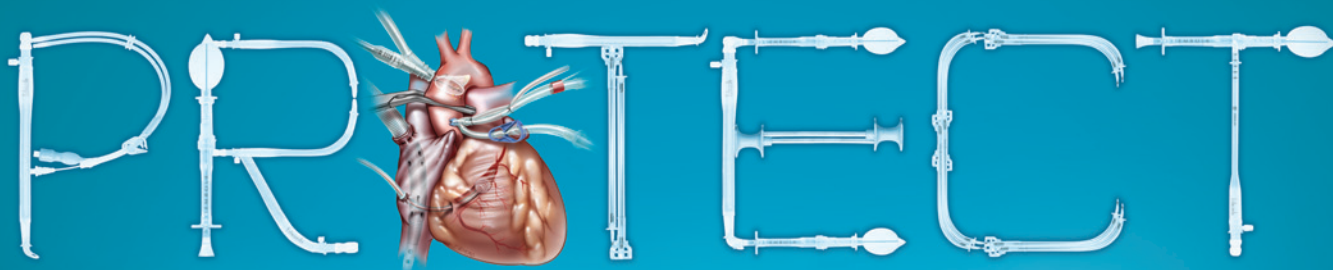
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Principles of physiologically-based Microplegia

Pressure, route, composition, flow control, temperature, additives and arrest are all critical principles of true physiologically-based Microplegia. The integrated protection strategy provides the ultimate metabolic environment and natural buffer (blood) with cardio-protective additives delivered to the myocyte and endothelium to manage and attenuate ischemia. The results of such comprehensive control is the restoration of normal metabolism and promotion of functional recovery. No other product is capable of providing this level of protection.

Route

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Composition

Oxygenated blood, natural buffers (Imidazole/Histidine) and oncotic pressure

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Precise, continuous or cyclic delivery

With so much control, the Quest MPS2 provides the opportunity to:

- Reduce myocardial edema
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- REDUCE COSTS



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Pressure

Auto-regulated response to ischemia, maximizes distribution as resistance changes

Temperature

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Arrest

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Call for a clinical evaluation and see why the MPS2 system is the fastest growing perfusion technology in cardiac surgery. Quest Medical offers hospital administrations several options for acquisition.

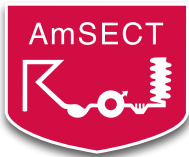


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Willingness to Serve Application 2011

Volunteering is a subject of paramount importance to our organization. AmSECT is dedicated to promoting and disseminating knowledge to our peer perfusionists around the world. Without volunteer leaders, our organization cannot fulfill this mission. Volunteering requires self-sacrifice and does not return any financial gain. However, the reward for giving back to our professional community is many-fold. AmSECT has improved itself throughout the years and continues to work with other organizations toward further progress in our industry. Without volunteers and their efforts, stagnation occurs, and this hurts us all. Please consider volunteering with AmSECT and set an example of leadership for other perfusionists and the future perfusionists of this rewarding profession we all love. As medical health care practitioners, our number one responsibility is patient welfare; our second responsibility may be improving the community in which we practice. All new and current members are encouraged to run for offices that are currently open for AmSECT. Your example will show all how much you care and will raise the bar for AmSECT.

Volunteer Leadership Positions Available

- ☐ **Director, Zone 1** – Three-year term. Zone 1 includes the following states: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, New Mexico, Nevada, Oregon, Utah, Washington, and Wyoming. Note: Alaska residents need not apply as Alaska is already represented on the Board of Directors.
- ☐ **Director, Zone 2** – Three-year term. Zone 2 includes the following states: Arkansas, Iowa, Illinois, Kansas, Louisiana, Minnesota, Missouri, North Dakota, Nebraska, Oklahoma, South Dakota, Texas, and Wisconsin. Note: Wisconsin residents need not apply as Wisconsin is already represented on the Board of Directors.
- ☐ **Director, Zone 4** – Three-year term. Zone 4 includes the following states: Connecticut, the District of Columbia, Delaware, Massachusetts, Maine, Maryland, North Carolina, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, South Carolina, Virginia, Vermont, West Virginia. Note: Maryland residents need not apply as Maryland is already represented on the Board of Directors.
- ☐ **Achievement Recognition Committee Member**
Three-year term. Member serves as Chairman in third year of term.
- ☐ **Ethics Committee Member**
Three-year term. Member serves as chairman in third year of term.
- ☐ **Nominating Committee Member**
Three-year term. Member serves as Chairman in third year of term.

All candidates must be AmSECT members in good standing to be considered for nomination. All volunteer leadership serving on any committee, or in any office of AmSECT, will be required to complete a Conflict of Interest Disclosure.

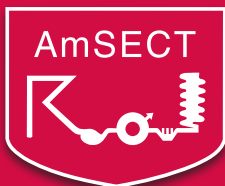
Willingness to Serve application and attachments must be submitted no later than November 30, 2010 to earn recognition on the ballot. Questions? Contact Nominating Committee member Mat Medlin, rtrccp06@yahoo.com

Submission Instructions

Willingness to Serve Applications must be filed online at <http://amsect.societyhq.com/members/wtsa.iphtml>.

In an effort to assist the Nominating Committee and the membership in making the selection, all candidates must submit the following:

- ☐ Biographical statement of 150 words or fewer to include:
 - Educational background
 - Job experience
 - AmSECT experience
- ☐ Statement of why you are running for this position, in 150 words or fewer
- ☐ Photograph of yourself



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BEST PRACTICES & SAFETY ?

CHALLENGE YOURSELF!

By Christina Burn CCP LP



Christina Burn CCP LP

1. **More than 90 percent of allogeneic blood transfusion complications have been attributed to which of the following:**
 - a. Leukocytes
 - b. Thrombocytes
 - c. Erythrocytes
 - d. Plasma
2. **Once a person has been infected with the HIV virus, how long is the general period between inoculation and seropositivity (using traditional screening tests)?**
 - a. 1 week
 - b. 3 weeks
 - c. 1 month
 - d. 6 to 12 weeks
3. **When stored properly, how long are red blood cells safe for infusion?**
 - a. Up to 21 days
 - b. Up to 30 days
 - c. Up to 42 days
 - d. Up to 56 days
4. **If not used properly, a gas scavenging line to scavenge waste gas from a hollow-fiber membrane oxygenator could inadvertently cause back pressure into the oxygenator. Such pressure could introduce gas into the blood phase resulting in an air embolism.**
True or False
5. **According to the Joint Commision's 2010 National Patient Safety Goals, which of the following is their number one goal?**
 - a. Improve the quality of care
 - b. Improve the accuracy of patient identification
 - c. Improve communication among caregivers
 - d. Improve safety of medication use
6. **Which of the following would be seen if there was a leak in the gas supply line to the CPB circuit?**
 - a. Bright red blood in the arterial line
 - b. Decreased CO₂ levels
 - c. Decreased PaO₂ levels
 - d. No change would be seen
7. **Which of the following abbreviations is incorrect and should NOT be used while charting?**
 - a. U for units
 - b. Mcg for micrograms
 - c. L for liter
 - d. % for percent
8. **A reported advantage of a centrifugal pump vs. a roller pump is a reduced risk of passing clinically significant amounts of air into the arterial line.**
True or False
9. **According to Gravlee, a minimum of how much air needs to be introduced into the circuit for a centrifugal pump to become deprimed and stop pumping?**
 - a. 12 mL
 - b. 25 mL
 - c. 32 mL
 - d. 45 mL

SELF QUIZ

10. A pregnant patient requiring CPB should be placed in a supine position with their left hip elevated, also known as a right lateral position.

True or False

11. Irreversible ischemic injury can become apparent with coronary occlusion in the working myocardium after how many minutes?

- a. 5 min
- b. 10 min
- c. 20 min
- d. 30 min

12. Protein denaturation and damage to the cellular portions of blood increases with a heater-cooler water temperature above 42 °C and a temperature below 4°C.

True or False

13. Of all the health risks to open heart team members, which of the following is the most serious risk?

- a. Bloodborne pathogens
- b. Blade cuts
- c. Needle sticks
- d. Back injuries

References:

AmSECT. 15 July 2010. <<http://www.amsect.org>>

Gravlee GP et al. *Cardiopulmonary Bypass*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins, 2008

International Board of Blood Management. 15 July 2010.
<<http://www.intbbm.org/>>

Pall Corporation. 15 July 2010. <www.bloodtransfusion.com>

2010 AmSECT Today Themes

| | |
|-------------------|--|
| January/February | Extended Life Support |
| March/April | Adjunctive Perfusion/Ancillary Perfusion Responsibilities AmSECT International Meeting Promotion |
| May/June | Emerging Technologies - Pharmacology |
| July/August | AmSECT International Meeting Summary Blood Management |
| September/October | Perfusion Safety/Best Practices in Perfusion |
| November/December | Pediatric and Congenital Perfusion |

AMSECT WELCOMES NEW MEMBERS

ACTIVE

| | |
|--------------------------------|------------------|
| James Buck CCP LP | Ft. Worth, TX |
| Robert Deyell BSc CCP | Orchard Park, NY |
| Stephen Garrett CCP | Draper, UT |
| Kellen C. Greenlee MS CP | Santa Monica, CA |
| Michele Heath | Alexandria, VA |
| Tom Irwin CCP | Lexington, KY |
| Greta L. Johnson CCP | Duluth, MN |
| Steve Learn CCP | Boonville, IN |
| Jamie W. Newberry BS | Shawnee, KS |
| Joseph Riviello CCP | Dunmore, PA |
| Dmitriy Rodom CCP | Springdale, PA |
| Ian D. Rosenberg BS | Pittsburgh, PA |
| Joseph T. Schlut CCP | Boulder, CO |
| James Serley CCP | Pensacola, FL |
| Thomas Q. Smith CCP | St. Louis, MO |
| Meghan Walsh | Wenonah, NJ |
| David M. West RN CCP | Cordova, TN |

ASSOCIATE

| | |
|-------------------------------|---------------|
| Susan L. Crutchfield RN | Nashville, TN |
| Ralph Rivera PharmD | Aurora, CO |

INTERNATIONAL

| | |
|--------------------------|----------------------|
| Hendrik Bernolet | Brussels, Belgium |
| Steve Beun | Brussels, Belgium |
| Albert DeBakker | Brussels, Belgium |
| Yoshiyuki Endo CE | Niigata-shi, Japan |
| Ingrid Lefevre CCP | Brussels, Belgium |
| Jeroen Lehen CCP | Brussels, Belgium |
| Luc Vermassen | Brussels, Belgium |
| Teng Siew Yan | Singapore, Singapore |
| Eoin Coleman | Cork, Ireland |

PERIOPERATIVE BLOOD MANAGEMENT CLINICIAN

| | |
|--------------------|-----------------|
| Deborah Reid | Idaho Falls, ID |
|--------------------|-----------------|

STUDENT

| | |
|---------------------------|------------------|
| Jessica L. Crane | Conroe, TX |
| Dana Hutchison | Penrose, NC |
| Carrie Kovalski | Santa Ana, CA |
| Marie Letourneau | Indianapolis, IN |
| Chelsea L. Starrett | Milwaukee, WI |

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and Educational Support
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Beverly Bernard
Graphic Design / Publications
Email: beverly@societyhq.com

AmSECT Awards!

AmSECT National Awards Nominations Accepted Through November 30, 2010

The Awards will be presented at AmSECT's 49th International Conference, April 13-16, 2011 in New Orleans, LA. Nominations must be received by November 30, 2010, and can be submitted by visiting the home page of www.amsect.org. Nominations are accepted from members only; for UserID and password reminders, please contact liz@amsect.org.

The Gibbon Award

The award is designed to honor a candidate making a significant contribution to the cardiopulmonary discipline interrelating with the field of extracorporeal circulation.

- * The specialty of the candidate is not a criterion for the award.
- * The significant contribution must be in, or relate to, the field of extracorporeal circulation.
- * The candidate may receive the award only once.
- * The award consists of a medal and a check in the amount of \$1,000.

AmSECT Award of Excellence

The Award of Excellence is presented annually to a perfusionist who demonstrates that work of excellence which best exemplifies creativity and intellectual honesty in perfusion. This award is presented for excellence in any area such as education, continuing education, research, publication or leadership.

- * The person receiving this award must be active in the field of extracorporeal technology and be a member of AmSECT.
- * No perfusionist may receive this award in two consecutive years.
- * The award consists of a plaque and a check in the amount of \$1,000.

AmSECT Perfusionist of the Year

The Perfusionist of the Year Award is presented annually to a perfusionist making significant contributions to the field of extracorporeal technology.

- * The award is presented based on a variety of reasons. Examples include excellence in the field of perfusion or extracurricular activities associated with the field of perfusion.
- * The award recipient must be active in the field of extracorporeal technology and must be a member of AmSECT.
- * No perfusionist may receive this award in two consecutive years.
- * This award is not to be presented for any one specific reason repeatedly, for there are many people in the field of extracorporeal technology making worthy contributions in a variety of areas who deserve recognition.
- * The award consists of a plaque and a check in the amount of \$1,000.



**AmSECT
Needs YOU!!
Get Involved!**



**Log into the Members Section at
www.amsect.org
to submit your nominations**

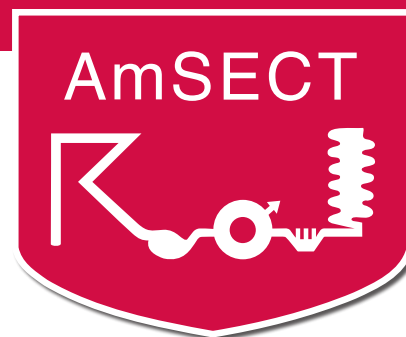
AmSECT PAST AWARD RECIPIENTS

Gibbon Award

| | |
|------|-----------------------------|
| 1974 | Dr. Clarence H. Dennis |
| 1975 | Dr. Charles A. Hufnagel |
| 1976 | Dr. Denton A. Cooley |
| 1977 | Dr. Clarence Crafoord |
| 1978 | Dr. John Osborne |
| 1979 | Dr. C. Walton Lillihei |
| 1980 | Dr. P. Galletti |
| 1981 | Dr. Arthur C. Beall |
| 1982 | Dr. Marian I. Ioniscu |
| 1983 | Dr. E. Coverse Pierce II |
| 1984 | Dr. Yukihiko Nose |
| 1985 | Dr. John Kirklin |
| 1986 | Dr. Norman Shumway |
| 1987 | James P. Dearing |
| 1988 | Dr. Henry Swan |
| 1989 | Dr. H. Edward Garrett |
| 1990 | Dr. Dwight C. McGoon |
| 1991 | Dr. W. Gerald Rainer |
| 1992 | Dr. Robert H. Bartlett |
| 1993 | Dr. Michael E. DeBakey |
| 1994 | LeRoy H. Ferries |
| 1995 | Bennett Mitchell |
| 1996 | Dr. Richard A. DeWall |
| 1997 | Dr. Theodor Kolobow |
| 1998 | Jeanne Lange |
| 1999 | Dr. Edward Verrier |
| 2000 | Dr. David C. Sabiston, Jr. |
| 2001 | Dr. Thomas B. Ferguson, Sr. |
| 2002 | Dr. O.H. Bud Frazier |
| 2003 | Michael W. Dunaway |
| 2004 | Dr. Robert F. Dunton |
| 2005 | Madeline M. Massengale |
| 2006 | O. Wayne Isom MD |
| 2007 | Ludwig K. von Segesser MD |
| 2008 | Gerald M. Buckberg MD |
| 2009 | Raymond Hawkins |
| 2010 | William J. DeBois CCP |

Award of Excellence

| | |
|------|------------------------|
| 1976 | Jeri L. Dobbs |
| 1977 | Edward C. Berger |
| 1978 | Charles C. Reed |
| 1979 | James P. Dearing |
| 1980 | Emily Taylor |
| 1981 | Gary Reeder |
| 1982 | Mark Kurusz |
| 1983 | Jerry Richmond |
| 1984 | Munier Jallad |
| 1985 | Nancy Achorn |
| 1986 | William J. Horgan |
| 1987 | Sandra S. Witherington |
| 1988 | Jeanne Lange |
| 1989 | Rebekah Trittipoe |
| 1990 | LeRoy H. Ferries |
| 1991 | Beverly Parault |
| 1993 | Aaron Hill |
| 1994 | Phyllis Palmer Stark |
| 1995 | Alfred H. Stammers |
| 1996 | Jeff Riley |
| 1997 | Dennis Rivard |
| 1998 | Robert D. Longenecker |
| 1999 | Ian R. Shearer |
| 2000 | Debbie Raymond |
| 2001 | Eric H. Jenkins |
| 2002 | Jeff Edwards |
| 2003 | Linda B. Mongero |
| 2004 | Joseph J. Deptula |
| 2005 | William E. Harris |
| 2006 | Craig Vocolka |
| 2007 | Ron Richards |
| 2008 | Paul C. Cappola |
| 2009 | David Fitzgerald |
| 2010 | Robert C. Groom |



Perfusionist of the Year

| | |
|------|------------------------|
| 1974 | Madeline M. Massengale |
| 1975 | Calvin R. Scott |
| 1976 | Charles C. Reed |
| 1977 | Larry W. Cavanaugh |
| 1978 | A. Earl Lawrence |
| 1979 | Diane Clark |
| 1980 | Bob Pfefferkorn |
| 1981 | Carl L. Freytag |
| 1982 | Nancy Achorn |
| 1983 | Michael B. Hurdle |
| 1984 | Scutter Newton |
| 1985 | LeRoy H. Ferries |
| 1986 | William J. Horgan |
| 1987 | Mary Hartley Winkler |
| 1988 | Sandra S. Witherington |
| 1989 | Susan Haubert |
| 1990 | Dennis R. Williams |
| 1991 | Rebekah Trittipoe |
| 1992 | Dennis Rivard |
| 1993 | Debbie Gherlone |
| 1994 | Craig R. Vocolka |
| 1995 | Beverly Parault |
| 1996 | James Langwell |
| 1997 | Richard Burns |
| 1998 | Carl Barringer |
| 1999 | Sherry C. Faulkner |
| 2000 | Ron Richards |
| 2001 | Linda B. Mongero |
| 2002 | Gary Grist |
| 2003 | John M. Toomasian |
| 2004 | Carla Maul Williams |
| 2005 | Gary Beckman |
| 2006 | Bruce Searles |
| 2007 | Joseph J. Deptula |
| 2008 | Susan J. Englert |
| 2009 | Bryan Lich |
| 2010 | Kenneth G. Shann |

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Appendix A.9

Hanuola - ECMO Program of Hawaii (176)

| <i>Unique ID</i> | <i>PatID</i> | <i>Run</i> | <i>Birthdate</i> | <i>Age</i> | <i>Date On</i> | <i>Date Off</i> | <i>D/C Alive</i> |
|------------------|--------------|------------|------------------|------------|----------------|-----------------|------------------|
|------------------|--------------|------------|------------------|------------|----------------|-----------------|------------------|

Pulmonary

Neonatal

| | | | | | | | |
|------------|-------|---|-----------------|--------|------------------|------------------|-------|
| 1762007001 | 36815 | 1 | 9/14/2007 22:51 | 6 Days | 9/20/2007 13:21 | 9/25/2007 16:20 | False |
| 1762007002 | 36944 | 1 | 10/8/2007 19:35 | 2 Days | 10/10/2007 10:03 | 10/14/2007 12:00 | True |
| 1762008001 | 37403 | 1 | 1/4/2008 6:49 | 1 Days | 1/5/2008 14:15 | 1/6/2008 14:42 | True |
| 1762008004 | 40359 | 1 | 11/25/2008 6:20 | 6 Days | 12/1/2008 11:33 | 12/13/2008 18:21 | True |
| 1762009001 | 40360 | 1 | 3/2/2009 17:00 | 1 Days | 3/3/2009 18:36 | 3/6/2009 12:52 | True |
| 1762009005 | 42413 | 1 | 9/2/2009 14:24 | 5 Days | 9/7/2009 7:21 | 9/11/2009 18:21 | True |
| 1762009006 | 42414 | 1 | 10/3/2009 9:44 | 1 Days | 10/4/2009 9:26 | 10/11/2009 13:07 | True |
| 1762009010 | 42418 | 1 | 11/25/2009 3:21 | 6 Days | 12/1/2009 18:15 | 12/2/2009 16:14 | False |
| 1762010001 | 43027 | 1 | 1/19/2010 20:00 | 2 Days | 1/21/2010 14:15 | 1/23/2010 12:39 | True |

Pediatric

| | | | | | | | |
|------------|-------|---|----------------|-----------|------------------|-----------------|-------|
| 1762009003 | 41215 | 1 | 3/29/2009 0:00 | 1 Months | 4/30/2009 16:17 | 5/19/2009 16:14 | False |
| 1762009004 | 41321 | 1 | 6/26/1995 0:00 | 14 Years | 7/25/2009 3:35 | 8/7/2009 14:46 | True |
| 1762009009 | 42417 | 1 | 2/29/2004 0:00 | 5 Years | 10/29/2009 17:52 | 11/17/2009 3:04 | False |
| 1762010002 | 43299 | 1 | 8/18/2007 0:00 | 31 Months | 3/9/2010 13:19 | 4/5/2010 10:15 | False |

Adult

Cardiac

Neonatal

| | | | | | | | |
|------------|-------|---|----------------|---------|-----------------|-----------------|------|
| 1762008003 | 39181 | 1 | 7/9/2008 16:20 | 10 Days | 7/19/2008 11:59 | 7/23/2008 10:00 | True |
|------------|-------|---|----------------|---------|-----------------|-----------------|------|

Pediatric

| | | | | | | | |
|------------|-------|---|-----------------|-----------|-----------------|-----------------|-------|
| 1762008002 | 37808 | 1 | 10/12/2000 0:00 | 7 Years | 3/14/2008 2:47 | 3/18/2008 14:54 | False |
| 1762009002 | 40715 | 1 | 1/11/2008 0:00 | 15 Months | 4/22/2009 7:31 | 4/26/2009 16:20 | True |
| 1762009007 | 42415 | 1 | 7/27/2009 0:00 | 3 Months | 10/12/2009 9:16 | 10/28/2009 8:30 | True |

ECPR

Pediatric

| | | | | | | | |
|------------|-------|---|-----------------|---------|------------------|------------------|-------|
| 1762009008 | 42416 | 1 | 11/24/2001 0:00 | 7 Years | 10/27/2009 17:08 | 10/29/2009 14:59 | False |
|------------|-------|---|-----------------|---------|------------------|------------------|-------|

Appendix B.1

ECMOjo Evaluation August 13 2010 Melody Kilcommons

Scenarios

Should we add comment if no bridge, or saline bridge, clamp arterial /clamp venous, then open bridge or add comment check your institutional guidelines? Not sure with partially open bridges, saline filled bridges and/or no bridge this is something that we should comment on or not?

Simulation 1

I think it works well. Perhaps decrease the amount of time for the scenario to start?

Simulation 2

Decannulation

Drops of blood coming from the neck

Success pathway – click baby and check for bleeding

I think there may need to be some consideration for those that think there is significant bleeding at the cannulation site, (which is what it looks like) they then clamp the circuit, go to emergency vent settings and give volume to the patient?

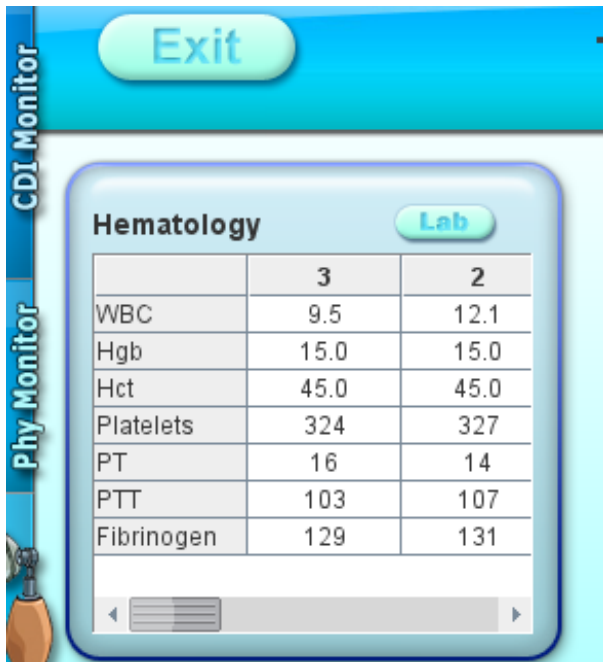
Can differentiate from patient bleeding and cannula site bleeding in ECMOjo?

3/5 said that they failed the first time choosing the above listed pathways instead of check for bleeding.

When you complete the scenario by checking for patient bleeding after you receive the ECMO results it makes sense and you can then pass.

Simulation 3

Feedback on this scenario was that each time you enter the scenario the labs change. I did it 7-8 times and I don't think the labs trigger the action that they should. Twice these were my labs 2 minutes into the scenario. I never gave fibrinogen or platelets.



The screenshot shows a medical simulation interface. At the top, there is a blue bar with a white 'Exit' button. Below this, on the left, are vertical labels 'CDI Monitor' and 'Phy Monitor'. The main area displays a 'Hematology' table with a 'Lab' button. The table has two columns of results, labeled '3' and '2'. The rows include WBC, Hgb, Hct, Platelets, PT, PTT, and Fibrinogen. A scroll bar is visible at the bottom of the table.

| | 3 | 2 |
|------------|------|------|
| WBC | 9.5 | 12.1 |
| Hgb | 15.0 | 15.0 |
| Hct | 45.0 | 45.0 |
| Platelets | 324 | 327 |
| PT | 16 | 14 |
| PTT | 103 | 107 |
| Fibrinogen | 129 | 131 |

If I give fibrinogen more than once, the CVP increases from 14 to 18 and an alarm goes off.

There are never clots in the circuit the circuit check is always ok.

The labs are always changing each I perform the scenario twice it worked the other 8 times the labs were not appropriate for this scenario, platelets were high normal.

When I change the circuit and one time the blood pressure was way too high and another time it was still at a mean of 28 and I had to give blood cells to get it up

The most frustrating thing about this scenario is that even after reading the ECMO results, I cannot pass this scenario. I tried over 12 times.

Participant feedback ~ No matter what they tried even after reading the ECMO results they could not illicit a "success"

Simulation 4

Good